California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA
Communication and Public Education Committee

Contact Person: Virginia Herold
(916) 574-7911

Time: 2:00 – 5:00 p.m.
Date: September 14, 2007
Place: First Floor Hearing Room
Department of Consumer Affairs
1625 N. Market Boulevard
Sacramento, CA 95834

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Karen Abbe at (916) 574-7946, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order 2 p.m.

1. Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care
2. Update Report of *The Script*
3. Development of New Consumer Brochures
4. Update on a Proposed Forum on Medicare Part D Plans
5. Medication Compliance Report by the National Council on Patient Information and Education
6. Board of Pharmacy Web Site Redesign
7. Miscellaneous Consumer Issues/Articles in the Media
8. Update on the Board's Public Outreach Activities

Adjournment 5 p.m.

Meeting materials will be on the board's Web site by September 7, 2007

Agenda Item 1

Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: September 7, 2007

To: Members, Communication & Public Education Committee

Subject: Update on the Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care

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BACKGROUND:

Four years ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The project involved UCSF students developing one-page fact sheets on diverse health care topics for public education.

An important objective of the fact sheets was to develop new educational materials for issues that emerge in the health care area and for which there is no or little written consumer information available. This would aid the interns who develop the materials and gain the experience of developing consumer informational materials. It also benefits the board, because it gains an invigorated set of public informational materials that are topical and not generally available.

The UCSF Center for Consumer Self Care works directly with the students to develop the fact sheets, which are then reviewed by faculty members and then by the board. The board distributes these fact sheets at community health fairs and has them available online. The fact sheet format is intended to be attractive whether printed or photocopied. Bill Soller, PhD, of the UCSF Center for Consumer Self Care is overseeing this project.

To date, nine fact sheets have been approved by the committee, as follows:

- Generic Drugs – High Quality, Low Cost
- Lower Your Drug Costs
- Is Your Medicine in the News?
- Did You Know? Good Oral Health Means Good Overall Health
- Have You Ever Missed a Dose of Medication?
- What's the Deal with Double Dosing? Too Much Acetaminophen, That's What!
- Don't Flush Your Medication Down the Toilet!
- Thinking of Herbals?
- Diabetes – Engage Your Health Care Team

These nine fact sheets have been translated into Spanish, Vietnamese and Chinese.

At the September 2006 committee meeting, Dr. Soller provided four new draft fact sheets, as follows:

- An Aspirin a Day? ... Maybe, Check it Out!
- Uncommon Sense for the Common Cold
- Medication Errors, Mistakes Happen ... Protect Yourself
- Putting the Chill on Myths about Colds and Flu

The committee recommended changes to the draft fact sheets in September 2006, which were provided to Dr. Soller. In January 2007, the board's new consumer outreach analyst Karen Abbe noted several additional changes that needed to be made to the draft fact sheets, and also requested annotated references to specific data contained in the fact sheets.

At the April 2007 Communication & Public Education Committee meeting, Dr. Soller provided edited versions of the four draft fact sheets. The edited versions contained some of the suggested changes, as well as new language not previously included. No annotated versions were provided for the committee.

Dr. Soller also provided additional (new) draft fact sheets for the committee's review and consideration:

- Preventing falls
- Is the site reliable?
- Your rights as a patient and consumer of healthcare!

Dr. Soller also referenced the following draft fact sheets under development. To date, the board's staff has not seen these items:

- Consumer reporting of adverse drug events
- Driving when you are taking medicines
- Tips for Parents
- Allergies to medicines

Following the June 2007 Public Education Meeting, Dr. Soller provided a draft fact sheet on pill-splitting.

UPDATE FOR THIS SEPTEMBER MEETING:

Since the April 2007 Communication and Public Education Meeting, board staff have sought corrections to these fact sheets, and hoped to have the corrected versions and the 12 proposed new fact sheets available for comment. However, as of this date, the board does not have these materials. Additionally, the nine (approved) fact sheets currently posted on the board's Web site contain a previous UCSF Center for Consumer

Self Care address. Select fact sheets posted to the UCSF Web site contain the board's previous address at 400 R Street and (both) UCSF's Parnassus Avenue and California Street addresses.

On August 9, Board Member Schell and I met with Dr. Soller at UCSF to discuss the future of the fact sheet series.

Dr. Soller indicated there is need for the Center for Consumer Self Care to be viable, and as such, some projects which formerly were produced without a stipend could no longer be pursued.

He proposed that while the Center for Consumer Self Care was interested in continuing to work with the board on developing fact sheets, they could no longer do so without a subsidy or some sort of subsidy. The suggestion was for the board to contract with UCSF to develop 16 fact sheets over the next year, for a fee of $25,000.

Since this August meeting, there has been no additional work on the pending fact sheets from UCSF. We have requested versions of the fact sheets that could modified, but have not received these items.

Meanwhile, at the June meeting of the committee, Board Members Schell and Ravnan and I agreed to contact California's other pharmacy schools to learn if they were interested in having their interns develop fact sheets in conjunction with the board, working under the auspices of board staff. A report of these contacts will be provided at this meeting.

The committee needs to determine what it wishes to do with respect to the fact sheet series. I believe that steps need to be taken to revitalize this project in some manner because this collaboration with interns holds the potential to benefit the board, the interns, and most especially the public.

Agenda Item 2

Update Report of *The Script*

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: September 7, 2007

To: Members, Communication & Public Education Committee

Subject: *The Script*

The next issue of *The Script* is planned for publication and distribution in January 2008. The focus of this issue will be on new laws, questions and answers about pharmacy practice asked of the board, and new regulation requirements. We will also include detailed information about e-pedigree implementation and the board's forthcoming fee increases.

The committee may wish to discuss items for future newsletters at this meeting.

Agenda Item 3

Development of New Consumer Brochures and Licensee Outreach Material

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: September 7, 2007

To: Members, Communication and Public Education Committee

Subject: Update on Development of New Consumer Brochures and Licensee Outreach Material

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Outreach Analyst Karen Abbe revised the text of some of the board's public education materials, and board staffer Victor Perez graphically designed the revised language. Refinements will be made to the materials at the request of the Communication and Public Education Committee (Committee) to ensure that the board's mission is reflected in all outreach materials.

1. Board of Pharmacy Overview Brochure and Complaint Brochure

   The Committee approved revised text for both brochures on April 3, 2007. The approved text was provided to the DCA Policy and Publications Development Office on April 11, 2007. DCA edited the brochure titles and text and prepared graphic layouts, which were provided for Committee review on June 27, 2007.

   Committee members noted arithmetic errors in DCA's graphic layout of the brochures, and expressed concerns about the language and images used. The changes made by DCA revealed a lack of understanding of what the board does. The Committee determined that both brochures should be reworked, using the language previously approved.

   Both brochures were modified, and graphic mockups were provided for review at the July 2007 Board Meeting. Copies of the overview brochure and complaint brochure are now available at the board's public counter, and will be distributed at future consumer outreach events and available on the board's Web site.

   Prior to printing additional copies, Committee input on language, color, and layout is encouraged for both brochures.

2. Prescription Drug Discount Program for Medicare Recipients

   Ms. Abbe revised the text included in the board's original brochure that was developed in response to SB 393 (Speier, Chapter 946, Statutes of 1999). This state program allows Medicare recipients to obtain medications at the Medi-Cal price if the patients pay out of pocket for the medication. The revised text

reflected the Medicare Part D Plan benefits that are now available to beneficiaries. The revised text was reviewed by the Committee on June 27, 2007. The Committee approved the revised language, but a meeting attendee questioned whether the state program was still in effect. Ms. Herold subsequently confirmed with the Department of Health Services that the state program is still in effect.

A graphic mockup is provided for review in the packet. Committee input on content and layout is encouraged. Refinements, if needed, will be made to ensure the accuracy of the information.

3. What You Should Know Before Buying Drugs From Foreign Countries or Over the Internet

   Minor revisions regarding the board's contact information were recently made to the English version of this brochure. The same revisions were made to the Spanish, Chinese, and Vietnamese versions of this brochure. Committee input on this document is encouraged to ensure that relevant and meaningful information is provided to the public. Revisions will be made at the Committee's request.

4. Pharmacist Licensure Information for Applicants

   There is a wealth of information on the board's Web site regarding instructions for the pharmacist exam, but some applicants do not read this information or perhaps do not retain it.

   Ms. Abbe has drafted a fact sheet geared towards graduates of U.S. Schools of Pharmacy, and a separate fact sheet geared towards foreign graduates who want to qualify for a pharmacist license in California. Both fact sheets are being reviewed by the Executive Officer, and drafts will be provided for review at the next Committee meeting.

   Meanwhile, attached is an article on pharmacist licensing information being written for the next issue of the CSHP magazine.

5. BOP Fact Sheet on Pill Splitting

   Absent a draft fact sheet from UCSF's Center for Consumer Self Care, Ms. Abbe drafted text on the subject of pill splitting. The text is geared towards consumers, and provides "dos" and "don'ts" on the practice of pill splitting. The Committee reviewed the proposed text on June 27, 2007. Committee Members and the public in attendance suggested revisions to the fact sheet, and revisions have since been made to the fact sheet.

Copies of the fact sheet will be distributed at future consumer outreach events and made available on the board's Web site. Additional revisions to the document will be made at the Committee's request.

6. BOP Fact Sheet on Counterfeit Drugs

   Ms. Abbe drafted a fact sheet geared towards consumers, and warning them about the prevalence of counterfeit drugs. This document is in draft form, and Committee input is encouraged to ensure that relevant information is provided to the public. Revisions will be made at the Committee's request.

7. BOP Fact Sheet on a Traveling Medicine Chest

   Ms. Abbe drafted a fact sheet geared towards consumers about items that may be helpful to bring when traveling. This document is in draft form, and Committee input is encouraged to ensure that relevant information is provided to the public. Revisions will be made at the Committee's request.

8. BOP Fact Sheet on Vaccinations and Travel Outside the United States

   Ms. Abbe drafted a fact sheet geared towards warning consumers about vaccinations as they relate to travel outside the United States. This document is in draft form, and Committee input is encouraged to ensure that applicable information is provided to the public. Revisions will be made at the Committee's request.

Where to find more information

The board's Web site provides consumer education material, application material for licensing, and information for ensuring compliance with California Pharmacy Law. The Web site also provides information on board meetings and critical forums vital to pharmacy services where public comments and input are encouraged. Go to www.pharmacy.ca.gov for materials including:

- Consumer Education Material
- Applications and Forms
- Complaint Resolution process
- Publications and Newsletters
- Pharmacy Law and Regulations
- License Verification
- Licensing Requirements and Renewal Information
- Public board and committee meeting dates, agendas, meeting materials and minutes

Did you know?

Anyone interested in receiving e-mail alerts about updates to the board's Web site can join the board's e-mail notification list. Go to to www.pharmacy.ca.gov, click on "Information For Consumers", then scroll to "Join our e-mail list." E-mail alerts provide information regarding:

- Regulations implemented or released for public comment
- Board newsletters when they are published
- Agendas for public meetings when released
- Questions and answers about new laws
- Board actions from board meetings

Consumers and licensees may also call or write to the board:

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(916) 574-7900

September 2007

STATE OF CALIFORNIA
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DEPARTMENT OF CONSUMER AFFAIRS

Healthy Californians

Through Quality Pharmacist's Care

California State Board of Pharmacy

Who we are

The California State Board of Pharmacy (board) serves the public as a consumer protection agency. The board is part of the Department of Consumer Affairs, which is in the executive branch of California's government. The Governor is at the top of the executive branch.

The board consists of 13 members, appointed to four-year terms. Members can serve only two consecutive terms. There are seven pharmacists and six public members appointed to the board. The Governor appoints the seven pharmacists, as well as four of the public members. The Senate Rules Committee and the Speaker of the Assembly each appoint one public member. Public members are individuals who are not licensed by the board.

Members of the board appoint the executive officer, who directs board operations and oversees a staff of more than 55 people. The staff includes over 20 pharmacists who inspect licensed premises and investigate suspected violations of pharmacy law. The board is self-funded through licensing fees, and receives no tax money from the General Revenue Fund of California.

How we protect the public

The board develops and enforces regulations to protect the public from the misuse and diversion of prescription drugs from pharmacies. The board licenses pharmacists, pharmacist interns, pharmacy technicians, and designated representatives (those involved with wholesaling medicine and medical devices, but who do not hold a pharmacist license).

The board also regulates firms that distribute medicine and medical devices in California. These firms include community pharmacies, hospital pharmacies, clinics, out-of-state pharmacies that fill prescriptions and deliver them to patients in California, and wholesalers who ship medicines into California.

To become a licensed pharmacist, an individual must graduate from an accredited pharmacy school, pass two examinations, and complete experience in both community and hospital pharmacies. In addition, continuing education is required for a pharmacist to renew his or her license.

What we do

Under California law, the board's mandate is consumer protection. The board oversees those that compound, dispense, store, ship, or handle prescription drugs and medical devices to patients and practitioners in California. Currently, the board licenses over 100,000 pharmacists, pharmacies, and other individuals and businesses who are involved in these activities. The board sets standards and licenses those who comply with these standards to ensure practitioners and businesses possess necessary skills and follow essential components.

The board ensures that pharmacists provide patients with quality pharmacist care when dispensing prescribed medicine, providing information to protect patients to prevent drug misadventures, and taking responsibility for therapeutic outcomes resulting from their decisions.

Did you know?

Information regarding license status and official actions taken in connection with a licensee, if known, are disclosed to the public upon request. You can obtain:

- Licensee Name
- License Number
- Name of Licensed Facility Owner (including the corporation name and corporate officers) and the Pharmacist-in-Charge
- Address of Record
- Date the original License was issued
- License Expiration Date
- Current License Status
- Letters of Admonishment
- Citations
- Referrals for formal Disciplinary Action
- Accusation/Petition to Revoke Probation
- Board Decisions
- Temporary Restraining Order
- Automatic Suspension Order
- Summary Suspension Order
- Interim Suspension Order
- Penal Code 23 license restrictions

HOW TO FILE A COMPLAINT

Complaint forms are found at www.pharmacy.ca.gov. The form may be filled out and submitted electronically, or the form can be printed and filled out by hand. The completed form must be sent to the California State Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. An on-line complaint form is also available on the Web site that can be submitted electronically.

WHAT HAPPENS TO MY COMPLAINT?

The board strives to complete most investigations within 120 days. Routine investigations may take up to 90 days, while more complex cases requiring extensive investigation may take longer.

If the complaint is within the board's jurisdiction, the complaint will be referred to staff for mediation or investigation. If the complaint is not within the board's jurisdiction, it may be closed with no action taken or referred to another agency that may have jurisdiction. A complaint could result in disciplinary action being taken against a licensee ranging from a reprimand, a citation and fine, or revocation of the license with loss of the right to practice or operate a pharmacy.

If you write to the board and request information regarding the outcome of a complaint, the board will respond in writing. The following information may be obtained:

- The date the complaint was received by the board
- A summary of the investigation
- The outcome or type of discipline

Formal disciplinary actions are a matter of public record, as are the names of licensees, their license numbers, their address of record, the date the original license was issued, and the current status (active or inactive) of that license.

CALIFORNIA STATE BOARD OF PHARMACY

FOR MORE INFORMATION ABOUT THE BOARD, LICENSING, OR THE COMPLAINT PROCESS, YOU MAY:

VISIT THE BOARD'S WEB SITE AT
WWW.PHARMACY.CA.GOV

WRITE TO THE BOARD AT
1625 N. MARKET BLVD., SUITE N-219
SACRAMENTO, CA 95834

CALL THE BOARD AT
(916) 574-7900

September 2007

STATE OF CALIFORNIA
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DO YOU HAVE A COMPLAINT?

California State Board of Pharmacy

COMPLAINT RESOLUTION

A primary way the California State Board of Pharmacy (board) protects the public is through the investigation of consumer inquiries and complaints involving the care patients have received. Errors in filling prescriptions or suspected misconduct by a pharmacist may be violations of pharmacy law, and should be reported, whether or not a patient was harmed. The board does not have jurisdiction over drug prices charged by the pharmacy or prescription billing disputes with insurance carriers.

The board advocates and enforces laws that protect the health and safety of patients, and encourages submission of complaints and inquiries from the public. Each complaint is evaluated to determine if the complaint involves a pharmacist, pharmacy, or firm regulated by the board, and whether the complaint involves a violation of California Pharmacy Law.

WHAT IS PHARMACIST MISCONDUCT?

Examples of misconduct by a pharmacist include (but are not limited to) instances where:

- The pharmacist fails to counsel you about how to take a new prescription medicine (or a prescription with changed instructions) and its possible side effects
- A non-pharmacist counsels you regarding your prescription
- A pharmacist is not present and your prescription is filled by a non-pharmacist
- A pharmacist fails to maintain the confidentiality of your prescription
- A pharmacist appears unable to function safely (due to alcohol or drug abuse)
- The pharmacy is dirty, cluttered, or looks unsanitary
- A pharmacist fails to assist you in obtaining a prescribed drug or device from another pharmacy, when the drug or device is out of stock
- A pharmacist fails to assist you in obtaining a prescribed drug or device from another pharmacy, when the pharmacist refuses to fill the prescription for ethical, moral, or religious reasons

WHAT ARE PRESCRIPTION ERRORS?

Examples of prescription error violations include (but are not limited to) instances where:

- Incorrect information is entered on the label of the prescription container
- A prescription is dispensed with the wrong drug or wrong dosage
- A prescription is refilled without proper authorization from the prescribing physician
- A generic drug is substituted for a brand name drug, without informing the patient of the substitution
- A prescription is filled using drugs whose expiration date has passed

A. Prescription pricing can differ from pharmacy to pharmacy under this program. Most of the time this will occur because different drug manufacturers charge Medi-Cal different prices for the same drug.

Q. I just refilled my prescription, and it cost more than last time, why?

A. Prescription drug manufacturers change their prices periodically. Price increases occur throughout the year, and for some drugs, many times during the year. Medi-Cal updates the prices it pays for drugs in its computer every month. If your prescription price does increase, you can ask your pharmacist if the manufacturer has increased the price.

Q. If I already have prescription coverage, will this program affect me?

A. The program covers Medicare patients who themselves pay the full drug price. If you have prescription drug coverage through an insurance plan, your pharmacy is not required to charge the insurance company the Medi-Cal price, even if you are a Medicare patient. However, if you have prescription coverage, it might be advantageous to use the program if:

- You have reached your yearly or monthly prescription maximum paid amount under your insurance program and now have to pay full price for your prescriptions.
- Your prescription insurance doesn't cover a certain drug prescribed for you.
- You have a deductible to meet before your coverage begins.

Q. Will this program affect my Medicare coverage?

A. No. This program does not affect your coverage under the Medicare program.

Q. Can I receive the Medi-Cal price from my mail order pharmacy?

A. Yes, if that pharmacy is a Medi-Cal provider.

Q. Who do I call if I believe the pharmacy is not charging me the right price, and I haven't been able to work it out with the pharmacy?

A. You can contact the California State Board of Pharmacy, Monday through Friday between the hours of 8 a.m. and 5 p.m. at (916) 574-7900.

Obtaining prices from several pharmacies may help you find the lowest cost, but it's best to get all your prescriptions from the same pharmacy. This way the pharmacist can record all the medications you are taking and what you are taking them for, and your pharmacist can tell you what to do if you have a bad reaction to a drug or find that a drug isn't working. Also, the pharmacist can check your new prescription to make sure it won't react badly with medicine you're already taking. Proper pharmaceutical care can protect your health or even save your life!

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September 2007

STATE OF CALIFORNIA
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DEPARTMENT OF CONSUMER AFFAIRS

Prescription Drug Discount Program for Medicare Recipients

You may be able to save up to 40% on the cost of your prescriptions not available under Medicare Part D, the Medicare Prescription Drug benefit. All you need is your Medicare card! California law makes it possible for Medicare recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal price for those drugs.

California State Board of Pharmacy

Here's how it works:

1. Show your Medicare card to the pharmacy staff.
2. Give your prescription to the pharmacy staff, and ask for the Medi-Cal prescription price. Ask if that is the lowest price the pharmacy will accept for the drug.
3. If the Medi-Cal price is the lowest price, you can pay that price, plus a small processing fee of 15 cents, for the prescribed drug. The processing fee is intended to reimburse the pharmacy for electronically checking Medi-Cal for prescription pricing information.
4. Pay for the prescription in full at the pharmacy. If you have prescription drug coverage, your insurance company is not eligible to receive the Medi-Cal price.
5. Only Medi-Cal provider pharmacies are required by law to offer and accept the Medi-Cal price as payment for prescription medication for Medicare recipients, but non-Medi-Cal pharmacies may also offer the Medi-Cal price if they choose.

Frequently Asked Questions

Q. What is the Prescription Drug Discount Program for Medicare Recipients?

A. It is a program that requires Medi-Cal provider pharmacies to charge Medicare recipients no more than the Medi-Cal price for their prescription drugs.

Q. Who is eligible?

A. Anyone who has a Medicare card is eligible. That includes seniors over age 65 and those under age 65 who are disabled and have a Medicare card. You do not have to be on Medi-Cal.

Q. Is Medi-Cal paying for my prescription?

A. No, Medi-Cal is not paying for the prescription. You, the Medicare recipient, are still responsible for paying for the prescription medication and the processing fee.

Q. Do I have to fill out any forms to take advantage of the program?

A. No. All you need is your Medicare card.

Q. Does the program work for drugs not covered under the new Medicare Part D benefit?

A. Yes. When you give your prescription to the pharmacist, show the pharmacy staff your Medicare card, and request the Medi-Cal price rate. The pharmacist will electronically check Medi-Cal for the price of the prescribed drug, and you will be eligible to buy the drug at that price, plus the 15-cent fee.

Q. How does the discount program work with telephoned prescriptions?

A. Ask the doctor's office to advise the pharmacy that you are a Medicare patient when they phone in your prescription. Then show your Medicare card when you pick up your prescription. For future prescriptions, it is also a good idea to ask your regular pharmacy to note on your record that you are a Medicare recipient.

Q. What drugs are covered?

A. Virtually every prescription medication is covered including both generic and brand name drugs; however, over-the-counter drugs and drugs that the pharmacist has to compound are not covered under this program.

Q. Can I go to any pharmacy I want to get the Medi-Cal price?

A. Only Medi-Cal pharmacy providers are required to charge a Medicare recipient no more than the Medi-Cal prescription price; however, most pharmacies in California do participate in the Medi-Cal program. Ask your pharmacy if it is a Medi-Cal provider. Some non-Medi-Cal pharmacies are willing to charge a similar prescription price.

Q. How much money will I have to pay?

A. What you pay will depend on the medication, but it will not exceed the amount Medi-Cal pays the pharmacy for the medication, plus the 15-cent processing fee.

Q. How much money will I save?

A. Again, that will depend on the medication, as well as the quantity ordered and the drug manufacturer. Several companies, with each charging a different price, may manufacture the same drug.

Q. How do I know I'm being charged the right amount?

A. Ask the pharmacist for a printout of the Medi-Cal information obtained through the pharmacy's computer. Be sure to make this request when you hand your prescription to the pharmacy staff or when the doctor's office calls in the prescription.

Q. I have called four different pharmacies and have received four different prices. Why is that?

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California State
Board of Pharmacy

Tel: (916) 574-7900
Web: www.pharmacy.ca.gov

What You Should Know Before Buying Drugs From Foreign Countries or Over the Internet

September 2007

Purchasing Prescription Drugs from Foreign Countries and Reducing Drug Costs

The prices of prescription drugs are high. Some patients go without food in order to purchase their medications or reduce the quantity of prescription drugs they are supposed to take to make a supply of medication last longer. Other patients simply don't purchase medication prescribed for them because it is too expensive.

Today, many patients are seeking lower priced drugs from nontraditional sources – places other than their local pharmacies. Some patients are purchasing prescription drugs from foreign countries, typically Canada or Mexico, because the prices are lower. Other patients are purchasing drugs online, from companies they do not know. Some patients purchase these drugs online without a prescription written for them by a health care provider.

Can you purchase drugs for lower prices? What should you know about purchasing drugs from foreign countries? What about purchasing drugs over the Internet? Do you really need a prescription before you obtain prescription drugs? The following information may help you in making wise choices.

Frequently Asked Questions

Q Can I bring prescription drugs I buy outside the USA into the country legally?

A The Federal Food and Drug Administration (the FDA) regulates prescription drugs made in the USA. Under federal law it is illegal for anyone except a drug manufacturer to import prescription drugs into the USA. There are strict requirements on drug manufacturers who import drugs.

These import laws were established for consumer protection – so that the only drugs available in the USA have been made by companies approved by the FDA, and have been manufactured at locations inspected by the government to produce the specific drugs. These laws are important for consistency – and uniformity – so that a specific drug has the same ingredients, strength, and will act in the same way regardless of who manufactures the drug or when the drug was made. This is important because it means the strength of the drug will be the same for every dose.

"Prescription drugs" means those drugs that are considered so dangerous that they may be sold only after a health care provider (for example, a doctor or nurse) has examined a patient and ordered the drug for the patient. The order is typically called a prescription. Consumers cannot legally purchase the prescription drugs without an order or prescription from a health care provider who has examined the

"Over the Counter Drugs" (or OTC drugs) are the drugs that you can buy without a prescription (for example, aspirin or cold medicines). Consumers can go to a store and select OTC drugs themselves.

Frequently Asked Questions (continued)

Such consistency in your medication is important for health care providers to treat you, and for you to receive the drug treatment planned and prescribed for you.

However, the FDA does not always enforce provisions for importing prescription drugs. Sometimes prescription drugs that are not FDA approved for sale in the USA are allowed in the USA on "humanitarian grounds" to treat serious conditions such as AIDS before the drugs are approved for use in the USA. Also, in the past the FDA has not enforced provisions against those who obtain a 90-day supply of medication for their personal use.

Q Why are prescription drug prices lower in other countries than here at home?

A There are a number of reasons. Among them: some governments set maximum drug prices for prescription drugs which holds down drug prices. In the USA, the government does not set maximum prices overall for prescription drugs. Also, typically the costs of researching and developing new drugs are passed on to American customers as part of a drug's price.

Q Why are prescription drug prices different at the local pharmacies in my neighborhood?

A There are a number of reasons – among them:

- *Volume discounts* -- some pharmacies can purchase drugs from wholesalers at lower prices than other pharmacies, based on the quantities of drugs sold or whether the pharmacy is part of a buying group with other pharmacies.
- *Rebates* – money is sometimes paid to pharmacies by drug manufacturers for sales of particular drugs. Not all pharmacies may get these rebates.
- *Overhead* -- charges that cover the expenses for the operations of the pharmacy and the services provided by the pharmacy.

Q Are the drugs I get from a foreign country lower in quality or strength?

A The drugs you obtain this way may be of the same quality as those you get in the USA – the prescription drugs may even have been manufactured here. However, you cannot tell what the drug is just by looking at it. If the drugs are counterfeit, are of a different strength, have been stored improperly or are not really the drugs the label says they are, a patient using such drugs could suffer serious health problems.

Is the Internet a good way to purchase prescription drugs?

Sometimes. Be cautious and careful.

- Make certain you are dealing with a pharmacy, and not another type or unknown form of drug supplier. Some businesses operating what appear to be Internet pharmacies are not pharmacies at all.
- Learn where the company is located – it may be located outside the USA in a country you know little about and where there is little government regulation of drug supplies.
- Beware if you do not need a prescription to purchase prescription drugs. The requirement for a prescription from a health care provider who has examined you is a legal requirement that exists to protect your health.
- Be careful if you must provide personally identifiable information (health information, social security number, credit card numbers) -- identity theft is a growing problem and you may not know to whom you are providing this sensitive and important personal information.
- Evaluate all costs for purchasing the drugs this way – it may not be cheaper after all.
- Purchase prescription drugs only from sites that are certified by national organizations – like the National Association of Boards of Pharmacy VIPPS seal on the Web site (the California Board of Pharmacy can help you with this information).
- Advise your health care provider if you obtain prescription drugs this way.

Before buying drugs from a foreign country or over the Internet, carefully consider your options.

- Beware of any changes in your health after taking any drug obtained this way. If there is a change or if you feel differently, talk to your health care provider.
- Consider whether you want to give a credit card number to a company that is making these purchases for you.
- Determine the handling and other extra fees you pay for imported prescription drugs. How much will you really save?
- Ask any company that orders prescription drugs for you what it will do if there is a problem with the medication you receive.
- Keep your health care provider informed.

For further assistance, please contact:

California State Board of Pharmacy
1625 North Market Blvd., Suite N219
Sacramento, California 95834
Phone: (916) 574-7900

Or visit us on the web at:
www.pharmacy.ca.gov

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加州
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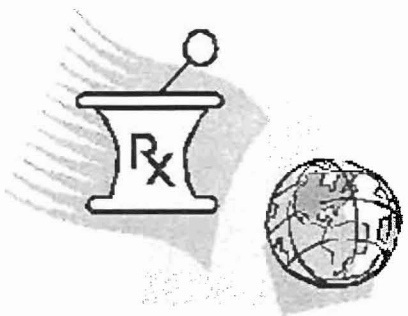
從國外或網際網路上購買藥品須知



2007 年9月

從國外購買處方藥品減少藥品費用

處方藥品價格昂貴。有些患者為了購買藥品省吃儉用，或者減少他們應當服用的處方藥品劑量，以延長藥品可服用時間。其他患者則因為藥品太貴而乾脆不購買開給他們的藥品。

目前，許多患者從非傳統來源（本地藥房以外的其他地方）尋找較低價格的藥品。有些患者從國外購買處方藥品，一般是加拿大或墨西哥，因為那裏的價格便宜些。其他患者則在網上從他們並不瞭解的公司那裏購買藥品。有些患者在沒有保健服務提供者所開處方的情況下在網上購買這些藥品。

您可以買到價格較低的藥品嗎？從國外購買藥品您應當瞭解什麼？可否考慮從網際網路上購買藥品？您在取得處方藥品前確實需要處方嗎？以下資訊可以幫助您做出明智的選擇。

常見問題

問 我可以合法地將從國外購買的處方藥品帶入美國嗎？

答 聯邦食品與藥品管理局 (FDA) 負責對美國製造的處方藥品進行管理。根據聯邦法律，除藥品製造商外，任何人將處方藥品進口到美國都是非法的。對於進口藥品的藥品製造商也有嚴格的要求。

制定這些進口法律是為了保護消費者——這樣在美國可以買到的藥品都是由 FDA 批准的公司所生產，並且是在政府視察過的地點生產有關藥品。這些法律對於藥品的一致性及均勻性是很重要的——這樣某一特定藥品，不管是誰製造或何時生產，都具有相同的成分、藥效強度並起到同樣的療效。這是很重要的，因爲這樣每一劑藥都會有同樣的藥效強度。

「處方藥品」是被認為有危險的藥品，因此只有在保健服務提供者（例如，醫生或護士）檢查了患者並且爲患者指定該藥品之後才可以出售。醫生的指定通常叫做處方。如果沒有已檢查過患者的保健服務提供者的指定或處方，消費者就不能合法購買該處方藥品。

「非處方藥品」（或稱OTC 藥品）是您無需處方即可買到的藥品（例如，阿司匹林或感冒藥）。消費者可以去藥房自行選購 OTC 藥品。

常見問題（續）

藥品的這種一致性對於保健服務提供者爲您提供治療以及您接受爲您計劃及指定的藥物治療都非常重要。

然而，FDA並不總是強制實施進口處方藥品的規定。有時候，未經FDA批准在美國銷售的處方藥品以「人道理由」進入美國，未獲批准在美國使用就開始治療像愛滋病之類的嚴重病況。此外，FDA以前未強制實施針對獲得90天藥品用量供個人使用的人士的規定。

問 為什麼其他國家的處方藥品價格比這裏的便宜？

答 有若干原因。其中包括：有些政府設定處方藥品的最高價格以控制藥價。在美國，政府總體來說並未設定處方藥品的最高價格。另外，研究和開發新藥品的費用通常也作為藥品價格的一部分轉嫁給美國消費者。

問 為什麼在我們鄰里社區當地藥房的處方藥品價格各不相同？

答 有若干原因——其中包括：

- *數量折扣*——根據所售藥品數量或該藥房是否屬於有其他藥房參加的採購集團的成員，有些藥房能以低於其他藥房的價格從批發商處購買藥品。
- *回扣*——有時候製造商會付錢給藥房來銷售特定藥品。並不是所有的藥房都能得到這些回扣。
- *管理費用*——補償藥房營運費用及所提供服務的收費。

問 我從國外購買的藥品是否品質或藥效強度比國內的要低？

答 您以這種方式獲得的藥品和在美國買到的藥品可能有同樣的品質——該處方藥品甚至可能就是這裏製造的。然而，您不能僅憑外觀來判斷這些藥品。如果藥品是假冒的、藥效強度不同、存儲不當或與藥品標籤不符，服用這種藥品的患者可能會遭受嚴重的健康問題。

網際網路是購買處方藥品的正確途徑嗎？

有時候吧。但是要小心謹慎。

- 要確定您是向藥房而非另一型態或未知形式的藥品供應商洽購。有些企業看似在營運網際網路藥房，而它們根本不是藥房。
- 要瞭解該公司位於何處——該公司或許位於美國以外一個您很陌生的國家，並且那裏很少有對於藥品供應的政府管制。
- 如果您不需要處方即可購買到處方藥品，則應小心。要求對您進行過檢查的保健服務提供者所開的處方是保護您健康的一項法律要求。
- 如果您必須提供個人身份資料（健康資料、社會保障號碼、信用卡號碼），則應小心，身份資料竊盜是一個日益嚴重的問題，而您或許並不知悉您是將這些敏感而重要的個人資料提供給誰。
- 評估所有按這種方式購買藥品的成本——可能這樣做結果不見得便宜些。
- 只從經過全國性組織認證的網站購買處方藥品——像是在網站上的「全國藥業管理局協會」VIPPS標章（「加州藥業管理局」可協助為您提供這項資訊）。
- 若您是以這種方式取得處方藥物，則應告知您的保健服務提供者。

在從國外或網際網路上購買藥品之前，要仔細考慮您的選擇。

- 在服用以這種方式獲得的任何藥品之後，要注意您的健康情況有無變化。如果有變化或您感覺有所不同，就告訴您的保健服務提供者。
- 考慮是否要把信用卡號碼告訴為您購買藥品的公司。
- 確定您為進口處方藥品所支付的處理費用及其他附加費用。您能真正節省多少錢？
- 向為您訂購處方藥品的任何公司詢問，如果您收到的藥品有問題，該公司會如何處理。
- 讓您的保健服務提供者及時瞭解情況。

欲獲得更多幫助，請聯絡：

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, California 95834
電話：(916) 574-7900

或訪問我們的網站：
www.pharmacy.ca.gov

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
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Comité de Farmacia del
Estado de California

Tel: (916) 574-7900
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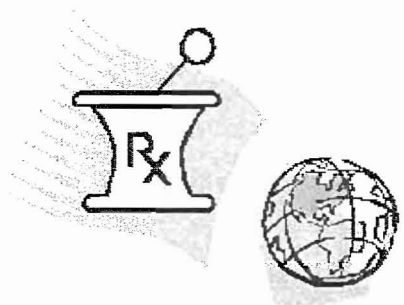
¿Qué necesita saber antes de comprar medicamentos de países extranjeros o por Internet?



Septembre 2007

Compra de medicamentos de prescripción (o por receta) de países extranjeros y reducción del costo de los mismos

Los precios de los medicamentos por receta son elevados. Algunos pacientes incluso reducen su alimentación con la finalidad de comprar sus medicinas o disminuyen la cantidad de los medicamentos recetados que supuestamente deberían tomar para hacer que los mismos les duren más. Otros pacientes simplemente no compran las medicinas que se les han recetado porque son muy caras.

Actualmente, muchos pacientes están buscando medicamentos con precios más reducidos a través de fuentes no tradicionales, en sitios distintos a sus farmacias locales. Algunos pacientes están comprando medicamentos por receta en países extranjeros, normalmente en Canadá o México, debido a que sus precios son más bajos. Otros pacientes están comprando sus medicamentos en línea, de compañías que no conocen. Algunos pacientes compran estos medicamentos en línea sin una receta por escrito que les haya entregado un médico.

¿Puede obtener medicamentos a precios más bajos? ¿Qué necesita saber acerca de la compra de medicamentos en países extranjeros? ¿Qué debe saber acerca de comprar medicamentos por Internet? ¿En verdad necesita una receta para obtener medicamentos de prescripción? La siguiente información le podrá ayudar a tomar decisiones inteligentes.

Preguntas frecuentes

P ¿Puedo introducir legalmente al país los medicamentos de prescripción que he comprado fuera de los Estados Unidos?

R La *Federal Food and Drug Administration* (la FDA) regula los medicamentos de prescripción fabricados en los Estados Unidos. De acuerdo con las leyes federales, es ilegal que cualquier persona, con excepción de los fabricantes farmacéuticos, importen medicamentos de prescripción a los Estados Unidos. Existen requisitos muy estrictos para los fabricantes farmacéuticos que importan medicamentos.

Estas leyes de importación se establecieron como protección para el consumidor, de modo que los únicos medicamentos disponibles en los Estados Unidos son los fabricados por las compañías que han recibido la aprobación de parte de la FDA, además de ser fabricados en instalaciones bajo inspección gubernamental para la fabricación de medicamentos específicos. Estas leyes son importantes por su consistencia y uniformidad, de modo que un medicamento específico contiene los mismos ingredientes y concentración, además de que su acción será la misma independientemente de quién haya fabricado el medicamento y cuándo. Estos es un factor muy importante debido a que esto significa que la actividad o fuerza del medicamento será la misma para cada una de las dosis.

"Medicamentos de prescripción (o por receta)" significa que estos medicamentos se consideran peligrosos, por lo que sólo deben venderse mediante receta de un profesional médico debidamente acreditado (por ejemplo, un médico o una enfermera) que previamente haya examinado al paciente y recetado el medicamento para el mismo. A la receta normalmente se le denomina prescripción médica. Los consumidores no pueden comprar legalmente los medicamentos de prescripción sin una receta de un profesional médico que haya examinado al paciente.

"Los medicamentos de venta libre" (o medicamentos OTC) son los medicamentos que usted puede comprar sin una receta o prescripción (por ejemplo la aspirina o los medicamentos contra la gripe). El consumidor puede ir directamente a la tienda o farmacia y comprar los medicamentos OTC.

Preguntas frecuentes (continuación)

Esta consistencia en sus medicamentos es importante para los profesionales médicos que le ofrecen un tratamiento, además de que usted recibe el tratamiento farmacológico planificado y prescrito especialmente para usted.

Sin embargo, la FDA no siempre puede prever la importación de medicamentos de prescripción. En algunas ocasiones los medicamentos de prescripción no aprobados por la FDA para su venta en los Estados Unidos tienen un permiso para su circulación en los Estados Unidos por "motivos humanitarios" para el tratamiento de condiciones serias como por ejemplo el SIDA, antes de que dichos medicamentos sean aprobados para su uso en los Estados Unidos de Norteamérica. Asimismo, en el pasado la FDA no había establecido disposiciones en contra de aquellos que obtenían un suministro de medicamentos por 90 días para su uso personal.

P ¿Por qué existen medicamentos de prescripción a precios más bajos en otros países en comparación a los que se obtienen en el mercado local?

R Existen diversas razones. Entre ellas podemos mencionar: algunos gobiernos establecen un precio máximo para los medicamentos por receta, lo cual reduce sus precios. En los Estados Unidos el gobierno no establece precios máximos globales para los medicamentos de prescripción. Asimismo, es normal que los costos de investigación y desarrollo se transfieran a los clientes en Norteamérica como parte del precio del medicamento.

P ¿Por qué los precios de los medicamentos por receta difieren en las distintas farmacias de mi localidad?

R Existen diversos motivos, entre los que se pueden mencionar:

- *Descuentos por volumen:* algunas farmacias pueden comprar medicamentos a mayoristas con precios más reducidos en comparación con otras farmacias, el descuento se basa en la cantidad de medicamentos vendidos o si la farmacia es parte de un grupo de compras junto con otras farmacias.
- *Reembolsos:* algunas veces los fabricantes pagan dinero a las farmacias por el número de ventas de un medicamento en particular. No todas las farmacias pueden obtener estos reembolsos.
- *Gastos generales:* cargos que cubren los gastos de operación de la farmacia y los servicios que ofrece.

P ¿Los medicamentos que obtengo de un país extranjero tienen una fuerza o calidad menor?

R Los medicamentos que usted obtiene de esta manera son de la misma calidad a los que obtiene en los Estados Unidos, incluso los podrían haberse fabricado aquí.
Sin embargo, usted no puede determinar la calidad del medicamento simplemente mirándolo. Si los medicamentos son falsificados o tienen una fuerza diferente, si se han almacenado de manera inadecuada o el medicamento no es el de la etiqueta, el paciente que los use puede sufrir problemas serios de salud.

¿Es la Internet un buen medio para la compra de medicamentos?

En algunas ocasiones. Tenga cuidado y tenga precaución.

- Asegúrese de que está realizando su compra en una farmacia y no con otro tipo de proveedor, o de un desconocido. Algunos comercios que aparecen en Internet en realidad no son farmacias, aunque así lo aparenten.
- Determine la ubicación de la compañía, podría estar localizada fuera de los Estados Unidos, en un país que usted no conozca y en donde existen muy pocas normas gubernamentales para el suministro de medicamentos.
- Tenga cuidado cuando no se le pide una receta para la compra de medicamentos de prescripción. La necesidad de una receta de un profesional médico que le haya examinado es un requisito legal establecido para proteger su salud.
- Tenga mucho cuidado cuando se le solicite información personal sensible (información acerca de su estado de salud, su número de seguro social, números de su tarjeta de crédito): el robo de este tipo de información es un problema creciente y es posible que usted no sepa a quién le está revelando esta información personal sensible e importante.
- Evalúe todos los costos que implica la compra de medicamentos de esta manera, podría no ser tan económico después de todo.
- Compre medicamentos de prescripción únicamente en los sitios que cuenten con certificación de organizaciones nacionales, como por ejemplo las que ostenten el sello de la National Association of Boards of Pharmacy VIPPS en su sito en Internet (California Board of Pharmacy puede ayudarle con esta información).
- Pida consejo de su profesional médico si obtiene medicamentos de prescripción por esta vía.

Antes de comprar medicamentos de un país extranjero o por Internet, considere con cuidado sus opciones.

- Manténgase al tanto de los cambios en su salud después de usar cualquier medicamento obtenido de esta manera. Si detecta cualquier cambio o se siente diferente, consulte a su doctor o profesional médico.
- Considere si desea darle su número de tarjeta de crédito a una compañía para que realice estas comprar por usted.
- Determine los costos adicionales por envío o cualquier otro cargo adicional que deba pagar por los medicamentos importados. ¿Cuál es en realidad su ahorro?
- Pregunte a la compañía a la cual ordena los medicamentos de prescripción qué debe hacer en caso de que se presenten problemas con el medicamento que usted reciba.
- Mantenga informado a su profesional médico o doctor de cabecera.

Para obtener más información, por favor póngase en contacto con:

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, California 95834
Teléfono: (916) 574-7900

O visite nuestra página en:
www.pharmacy.ca.gov

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
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Hoäi Ñoàng Döôïc Khoa
Tieau Bang California

Ñieän thoaïi: (916) 574-7900
Maïng: www.pharmacy.ca.gov

Nhöõng gì caàn bieát tröôùc khi mua thuoác töø ngoaïi quoác hay trong maïng Internet

Thaùng Chín 2007

Mua thuoác theo toa töø ngoaïi quoác vaø giaûm chi phí thuoác men

Giaù thuoác theo toa raát maéc. Moät soá beänh nhaân phaûi boû aên môùi coù theå mua ñöôïc thuoác, hay phaûi giaûm soá löôïng thuoác theo toa maø hoï phaûi uoáng ñeå coù tieáp lieäu thuoác laâu hôn. Nhieàu beänh nhaân khaùc khoâng mua thuoác baùc só cho toa vì chuùng quaù maéc.

Ngaøy nay, nhieàu beänh nhaân tìm thuoác giaù thaáp beân ngoaøi – töø nhöõng nôi khaùc hôn laø döôïc phoøng ñöa phöông. Moät soá beänh nhaân mua thuoác töø caùc quoác gia khaùc nhö Gia Naõ Ñaïi hay Meã Taây Cô, vì giaù reû hôn. Moät soá beänh nhaân khaùc mua thuoác tröïc tuyeán, töø caùc coâng ty hoï khoâng töøng bieát ñeán. Moät soá beänh nhaân mua caùc thuoác naøy tröïc tuyeán maø khoâng coù toa baùc só.

Quyù vò coù theå mua thuoác reû khoâng? Nhöõng gì caàn bieát khi mua thuoác ngoaïi quoác? Coøn mua thuoác tröïc tuyeán trong Internet thì sao? Quyù vò coù thöïc söï caàn toa thuoác ñeå mua thuoác theo toa? Thoâng tin sau ñaây coù theå giuùp quyù vò tìm choïn löïa khoân ngoan hôn.

Caùc thaéc maéc thoâng thöôøng

H Toâi coù theå mang thuoác theo toa mua töø quoác gia khaùc ngoaøi Hoa Kyø vaøo nöôùc hôïp phaùp khoâng?

Ñ Cô Quan Y Teá Lieân Bang (Federal Food and Drug Administration, hay FDA) ñieàu haønh thuoác mua theo toa cheá bieán trong Hoa Kyø. Theo luaät lieân bang, ngöôøi naøo khaùc haõng cheá bieán thuoác nhaäp caûng thuoác vaøo Hoa Kyø laø ñieàu phaïm phaùp. Coù raát nhieàu quy luaät nghieâm khaéc cho haõng cheá bieán thuoác naøo nhaäp caûng thuoác.

Caùc luaät nhaäp caûng naøy ñöôïc thaønh laäp ñeå baûo veä ngöôøi tieâu duøng – chæ coù caùc thuoác coù trong Hoa Kyø ñöôïc cheá bieán töø caùc coâng ty ñöôïc FDA chaáp thuaän, vaø ñaõ ñöôïc cheá bieán töø caùc ñöa ñieåm ñöôïc chaùnh quyeàn thanh tra ñeå saûn xuaát caùc thuoác ñaëc thuø. Caùc luaät naøy raát quan troïng cho muïc ñích nhaát quaùn – vaø ñoàng daïng – ñeå moãi loaïi thuoác ñaëc thuø coù cuøng thaønh phaàn, ñoä maïnh, vaø seõ coù taùc duïng gioáng nhau baát keå haõng naøo saûn xuaát thuoác hay khi naøo thuoác ñöôïc cheá bieán. Ñieàu naøy raát

Thuoác theo toa" coù nghóa laø caùc thuoác ñöôïc xem laø nguy hieåm vaø chæ ñöôïc baùn cho beänh nhaân sau khi hoï ñöôïc nhoùm chaêm soùc söùc khoûe (thi duï nhö baùc só hay y taù) khaùm vaø ban leänh cho thuoác. Leänh cho thuoác thöôøng ñöôïc goïi laø moät toa thuoác. Ngöôøi tieâu duøng khoâng theå mua thuoác theo toa hôïp phaùp neáu khoâng coù leänh cho thuoác hay toa thuoác töø nhoùm chaêm soùc söùc khoûe ñaõ khaùm beänh nhaân.

"Thuoác mua khoâng caàn toa" (Over the Counter Drugs, hay OTC) laø caùc thuoác coù theå mua maø khoâng caàn phaûi coù toa thuoác (thí duï nhö aspirin hay thuoác caûm cuùm). Ngöôøi tieâu duøng coù theå ñi ñeán tieäm vaø töï choïn thuoác OTC.

Caùc thaéc maéc thoâng thöôøng (tieáp theo)

Taùnh chaát nhaát quaùn cuûa thuoác raát quan troïng cho caùc nhoùm chaêm soùc söùc khoûe trong vieäc chöõa trò cho quyù vò, vaø ñeå thuoác chöõa trò ñöôïc hoaïch ñònh vaø ñöôïc cho toa chæ rieâng cho quyù vò.

Tuy nhieân, FDA khoâng thöïc thi chaët cheõ caùc ñieàu khoaûn veà nhaäp caûng thuoác theo toa. Ñoâi khi caùc thuoác theo toa khoâng ñöôïc FDA chaáp thuaän cho baùn trong Hoa Kyø, laïi ñöôïc cho pheùp vaøo Hoa Kyø vì "lyù do nhaân ñaïo" ñeå chöõa trò caùc beänh nghieâm troïng nhö AIDS tröôùc khi thuoác ñöôïc chaáp thuaän cho söû duïng chaùnh thöùc trong Hoa Kyø. Ñoàng thôøi, trong quaù khöù FDA cuõng khoâng kieåm soaùt caùc ñieàu khoaûn ñoái vôùi nhöõng ngöôøi mua thuoác 90-ngaøy tieáp lieäu ñeå söû duïng caù nhaân.

H Taïi sao thuoác theo toa reû hôn trong caùc nöôùc khaùc so vôùi trong nöôùc?

Ñ Coù nhieàu nguyeân nhaân, trong soá ñoù laø: moät soá chaùnh quyeàn ñònh giaù toái ña cho thuoác theo toa, ñeå giöõ giaù thuoác thaáp. Trong Hoa Kì chaùnh quyeàn khoâng ñònh giaù toái ña cho thuoác theo toa. Ñoàng thôøi, chi phí nghieân cöùu vaø phaùt trieån thuoác môùi ñöôïc chuyeån qua cho ngöôøi tieâu duøng Hoa Kyø, naèm trong moät phaàn cuûa giaù thuoác.

H Taïi sao giaù thuoác theo toa khaùc hôn taïi caùc döôïc phoøng ñöa phöông trong laùng gieàng?

Ñ Coù nhieàu nguyeân nhaân, trong soá ñoù laø:

- *Giaûm giaù theo khoái löôïng* -- moät soá döôïc phoøng coù theå mua thuoác töø caùc ñaïi lyù thaáp hôn so vôùi caùc döôïc phoøng khaùc, döïa treân soá löôïng thuoác baùn, hay döôïc phoøng ñoù coù naèm trong nhoùm mua vôùi caùc döôïc phoøng khaùc hay khoâng.
- *Haï giaù* – Ñoâi khi caùc döôïc phoøng ñöôïc caùc haõng cheá bieán traû tieàn laïi khi hoï baùn moät soá thuoác ñaëc thuø. Khoâng phaûi döôïc phoøng naøo cuõng ñöôïc caùc haï giaù naøy.
- *Toång phí* -- tieàn tính trang traûi cho caùc chi phí ñieàu haønh cuûa döôïc phoøng vaø dòch vuï hoï cung öùng.

H Thuoác toâi mua töø ngoaïi quoác coù chaát löôïng hay ñoä maïnh thaáp hôn khoâng?

Ñ Thuoác quyù vò mua theo caùch naøy coù theå cuøng chaát löôïng so vôùi thuoác mua trong Hoa Kyø – thuoác theo toa raát coù theå cuõng ñöôïc cheá bieán taïi ñaây. Tuy nhieân, quyù vò khoâng theå phaân bieät ñöôïc thuoác khi chæ nhìn beà ngoaøi. Neáu thuoác naøy ñöôïc cheá laãu, coù ñoä maïnh khaùc, ñöôïc löu tröõ khoâng ñuùng caùch hay khoâng phaûi thöïc söï laø thuoác nhaõn hieäu cho bieát, beänh nhaân coù theå laâm vaøo tình traïng söùc khoûe nghieâm troïng.

Internet coù phaûi laø moät caùch toát ñeå mua thuoác

Ñoâi khi. Nhöng neân deø daët vaø thaän troïng.

- Neân bieát mình mua qua moät döôïc phoøng naøo, khoâng neân qua moät nhoùm cung öùng khoâng teân tuoåi. Moät soá kinh doanh ñieàu haønh theo hình thöùc döôïc phoøng Internet, nhöng hoï hoaøn toaøn khoâng phaûi laø moät döôïc phoøng.
- Tìm hieåu xem coâng ty ñoù ôû ñaâu – hoï coù theå naèm ôû ngoaøi Hoa kyø, trong moät quoác gia quyù vò raát ít bieát ñeán, vaø nôi ñoù coù raát ít chaùnh quyeàn ñieàu haønh treân thuoác tieáp lieäu.
- Neân caûnh giaùc khi quyù vò khoâng caàn toa thuoác ñeå mua thuoác theo toa. Baét buoäc phaûi coù toa thuoác töø nhoùm chaêm soùc söùc khoûe khaùm quyù vò laø moät ñoøi hoûi phaùp lyù ñeå baûo veä söùc khoûe cho quyù vò.
- Neân caån thaän khi phaûi cho thoâng tin caù nhaân (thoâng tin veà söùc khoûe, soá an sinh xaõ hoäi, soá theû tín duïng) -- aên caép teân tuoåi laø moät vaán ñeà ñang taêng vaø quyù vò khoâng bieát ngöôøi mình cho caùc thoâng tin kín ñaùo vaø thoâng tin caù nhaân quan troïng naøy laø ai.
- Chieát tính moïi chi phí ñeå mua thuoác theo caùch naøy – roát cuoäc roài chuùng coù theå khoâng reû hôn.
- Chæ mua thuoác theo toa töø caùc ñöa chæ maïng löôùi ñöôïc caùc toå chöùc quoác gia chöùng nhaän – nhö coù moäc cuûa Hieäp Hoäi Hoäi Ñoàng Döôïc Khoa (National Association of Boards of Pharmacy VIPPS) trong maïng löôùi (Hieäp Hoäi Hoäi Ñoàng Döôïc Khoa coù theå giuùp laáy thoâng tin naøy).
- Cho nhoùm chaêm soùc bieát mình mua thuoác theo caùch naøy.

Tröôùc khi mua thuoác töø ngoaïi quoác hay Internet, neân thaän troïng cöùu xeùt caùc choïn löïa.

- Neân caûnh giaùc baát cöù thay ñoåi gì veà söùc khoûe cuûa mình sau khi duøng thuoác mua theo caùch naøy. Neáu coù gì thay ñoåi hay coù caûm giaùc khaùc laï, neân baøn thaûo vôùi nhoùm chaêm soùc.
- Cöùu xeùt kyõ xem coù neân cho soá theû tín duïng cuûa mình cho coâng ty seõ mua thuoác cho mình theo caùch naøy hay khoâng.
- Chieát tính phuï phí goùi haøng vaø caùc leä phí khaùc phaûi traû ñeå nhaäp caûng thuoác. Quyù vò thöïc söï tieát kieäm ñöôïc bao nhieâu?
- Hoûi coâng ty mua thuoác theo toa cho quyù vò laø hoï seõ laøm gì neáu quyù vò bò vaán ñeà vôùi thuoác mình mua.
- Caäp nhaät thöôøng xuyeân vôùi nhoùm chaêm soùc söùc khoûe

Muoán ñöôïc hoã trôï theâm, xin lieân laïc:

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, California 95834
Ñieän thoaïi: (916) 574-7900

Hay vieáng chuùng toâi taïi ñöa chæ:

Becoming a Licensed Pharmacist in California

An Insider's View

The California State Board of Pharmacy licenses pharmacists in California. The goal of licensing is consumer protection: the board is required to ensure that before practicing pharmacy, every applicant meets the minimum requirements. Once proof of achievement of the requirements is provided to and approved by the board, the board issues the individual a pharmacist license.

Pharmacy is regulated at the state level, so states have their own licensure requirements, although most states have similar requirements.
Each requirement has a purpose. The requirements themselves have their origin in California statutory laws (enacted by the Legislature) or in regulations (rules promulgated by the board).

For many applicants, the process will take four to five months. For others it will take six months, and for a few, longer than six months. Most applicants can take steps to minimize the timeframe required to become licensed to the shorter end of the range. This article describes these steps.

Here are the basic components (note: please use the directions for the online examination application to provide you with the specifics of each component). The more complete your application is when you submit it, the shorter the process will be for you.

I. BECOMING ELIGIBLE TO TAKE THE EXAMINATIONS:

1. EDUCATION: each applicant must be either:
   - A graduate of an ACPE-accredited school of pharmacy, or
   - If a foreign-educated pharmacist, certified by the Foreign Pharmacy Graduate Education Committee.

2. EXPERIENCE: each applicant must provide proof of experience working as an intern pharmacist or if licensed in another state, experience as a pharmacist. Satisfactory evidence of experience must be one of the following:
   - 1,500 hours of intern experience provided on affidavits available from the board if registered in California as an intern.
   - 1,500 hours of intern experience earned as a pharmacist intern in another state – these hours must be certified by the board of pharmacy in the state where the hours were earned.
   - Proof of licensure as a pharmacist in another state for one year – this requires a license certification from the board of pharmacy in the state where the individual is licensed.

3. CRIMINAL BACKGROUND CHECK: All pharmacist applicants must undergo a criminal background check by submitting fingerprints for evaluation by the California Department of Justice and Federal Bureau of Investigation. Even if you have previously submitted prints to the California board for an intern or pharmacy technician license, you must submit new prints with the classification of "pharmacist" listed on the fingerprint form. There are two ways to submit fingerprints:
   - If you are located in California, you must submit prints via LiveScan. This is faster, and the California Department of Justice is insistent that LiveScan be used for those residing in California.
   - If you are outside California, request that the board mail you fingerprint cards. You need to submit two cards along with a separate fee (made payable to the Board).
4. LICENSE VERIFICIATION: we require a license verification from every state in which you are licensed as a pharmacist. The state boards of pharmacy in the respective states need to provide these certifications.

II. BEING MADE ELIGIBLE FOR THE EXAMINATIONS:

Once the board has a complete application, the board will make you eligible to take the CPJE and NAPLEX exams. We will send you a letter notifying you that you are "eligible," and how to schedule your CPJE and NAPLEX exams. You can take the exams in any order.

- The board does provide some leeway for fingerprint clearances: if we have proof you have submitted prints for a pharmacist license, we will make you eligible without having the background clearances (however, you will not be licensed until we receive the clearances).
- If you passed the NAPLEX after January 1, 2004, you will not need to retake this examination if NABP can transfer the score to California. Contact NABP (www.nabp.net) for more information on how to share prior NAPLEX scores with California.
- Unless we have a quality assurance review (see below) underway for the CPJE, we will mail the scores to you typically within 14 days of when you take the exams.

III. BECOMING LICENSED:

After the board has the two passing scores on the required examinations, the board will send you a green sheet titled "Request for Issuance of Pharmacist License." You will be asked for a license fee and advised of any deficiencies remaining in your application. Typically the only deficiencies at this stage are results to the background clearances. If you believe that you have already corrected the deficiency, use the "Contact Us" feature from the board's Web site to email us or attach a note to the green sheet when you return it to the board.

We try to process these applications very quickly. The fastest way to know you are licensed is to use the license verification feature on the Web site (http://www.pharmacy.ca.gov/verify_lic.htm) and checking your name. Once your name appears as a licensed pharmacist, you are licensed. California law provides that verification of licensure from the Web site is proof you are licensed. You will receive a green, wallet-size license in about 8 weeks (another agency prints and mails these for the board). The large wall license will be mailed within four months.

TIPS for faster and smoother processing, remember:

1. Use one of the processes we suggest for verifying that the board received your application.
2. Status checks are a problem for the board to perform. It diverts limited staff away from processing activities to simply answering a question for someone. We will not generally respond to status inquiries on applications that are less than 60 days old with the board. Instead we direct staff to process applications. Please be patient – and use a technique listed elsewhere in this article to make certain you know we received your application.
3. However, there are times when applicants need to reach us. Use the appropriate email address under "Contact Us" on the Web site. Certainly email the board if it has been more than 60 days, and you have heard nothing from the board -- this is a problem you need to call to our attention. Also, if it has been more than 30 days after you believe your deficiency has been corrected, contact us.
4. If you receive a letter advising you that the board is missing some items (what we call a "deficiency letter") – this truly means we do not have the listed items. To get through the system faster, you need to provide the item, even if you may think we already have it. So what is most often missing?
    - Transcripts from colleges with the pharmacy degree posted (these must come directly from the school of pharmacy to the board). Oddly, some colleges do not post the PharmD degree to transcripts until 2-3 months after graduation.
    - Fingerprint clearances are sometimes a problem (we run both federal and state background checks). Sometimes we need to ask applicants to resubmit prints because something is preventing the board from receiving the documentation; the board will contact you if additional information is required.
    - Intern hours are missing or less than the 1,500 hours required.
5. Make certain your name matches identically on your government identification, with your social security card and with your name of record that you file with the board (this is the name that will appear on your pharmacist license). Identically means identically (see the board's Web

site for more information). Resolving name conflicts is the one area where you should not wait 60 days before resolving the problem.

6. The board periodically conducts quality assurance reviews of the CPJE. When this occurs, no CPJE scores are released until the assessment is completed. The board makes every effort to release scores as soon as we can, but a quality assurance check usually runs 2-3 months or until approximately 400 individuals take the test. We know this is frustrating, but it is necessary. We post this information on the Web site.

7. Background checks – if you have a prior conviction, you need to disclose it in the required place on the application and describe it fully. (You need to do this if you have reported the conviction on prior applications.) Even if you think a conviction has been expunged or set aside and dismissed, the clearance check usually picks up these records. If you state you have no convictions and yet a background check shows you do, this will be come an "enforcement issue." Enforcement issues will delay the processing of your application or issuance of a license until all enforcement matters are resolved (typically this adds at least two months).

What can you do?

1. Submit as complete an application as you can. This means you should submit in one package:
   - All required application forms
   - The required fee
   - Proof of at least 1,500 hours of intern experience
   - Verifications of pharmacist licensure from all states in which you are licensed
   - LiveScan Receipt showing submission of your fingerprints or if you are out-of-state, enclosing the fingerprint cards and additional processing fee.

2. How to verify the board has received your application:
   - Enclose a self-addressed, stamped post card or simply an envelope addressed to you with your application package. Board staff will mail these to you when the board receives your application -- so you know we have your application.
   - Check to see if the bank has cashed your check. The board cashiers all checks it receives very quickly – within two working days of receipt. If the check has been cashed, we received your application.

3. Contact us if it has been more than 60 days since you submitted your application and you have heard nothing from the board, or more than 30 days since you have taken steps to correct a deficiency and you have had no response from the board.

The board wants all qualified applicants to become licensed as quickly and effortlessly as possible. Use the information above to aid you in getting though the process as expediently as possible.

CALIFORNIA STATE
BOARD OF PHARMACY

BE AWARE & TAKE CARE:
Talk to your pharmacist!

Pill Splitting

...not for every person, and not for every pill

Splitting one pill into two pieces can help when a larger pill is hard to swallow, but the most common reason that pills are split is cost. Dividing one higher dose pill into two lower doses can result in less total cost (or fewer co-payments) because some manufacturers price higher dose pills at the same price as lower dose pills.

That doesn't mean all medicine can be split safely. The decision to split or not split a pill should be made after you understand the issues and your medicine. Ask your prescriber or pharmacist if pill splitting is appropriate for you.

DO

- Talk to your pharmacist and prescriber about whether your medicine can be safely split
- Use a device designed to split pills; splitters are available from $3 to $15
- Remember that air and moisture can affect a split pill, so splitting should occur only one pill at a time
- Take one piece of a split pill at one dosing, and the other piece at the next dosing time
- Split pills only if you are motivated to do so
- Ask your prescriber or pharmacist whether the correct dose is available without splitting a pill

DON'T

- Don't split pills that crumble
- Don't split pills if you have trouble with dexterity, poor eyesight, memory, or a condition that affects your ability to make decisions
- Don't split time-release pills because the premature exposure to stomach fluids may affect the medicine
- Don't split all pills from a prescription at one time because prolonged exposure to air and moisture may change the pills' effectiveness
- Don't split capsules
- Don't split small pills or unusually shaped pills
- Don't split pills with a knife or anything else that can cause an uneven split

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July 2007

DRAFT
9/7/07

CALIFORNIA STATE
BOARD OF PHARMACY

BE AWARE & TAKE CARE:
Talk to your pharmacist!

Counterfeit Drugs

Counterfeit drugs may look real, so be careful. The drugs may have too much or not enough of the medicine you need. Counterfeit drugs can be contaminated, diluted, or repackaged showing the wrong dose or expiration date.

If you take counterfeit drugs, you may have an allergic reaction and your medical condition can get worse. Counterfeit prescription drugs are illegal. Your risk of buying counterfeit drugs increases by buying medicine on the Internet because there is no face-to-face contact.

Tips to Avoid Counterfeit Drugs

- Buy your medicine from a U.S. state licensed pharmacy. Find your state's contact information from the National Association of Boards of Pharmacy at www.nabp.info. For California, go to www.pharmacy.ca.gov and click on "Verify a License" to determine whether the pharmacy is currently licensed.

- If buying medicines on the Internet, see if the Web site has the Verified Internet Pharmacy Practice Sites (VIPPS) Seal. A VIPPS seal means the site is a licensed pharmacy where FDA-approved medicines can be bought.

- Pay attention to the drugs you take and their effects. Has your medicine changed in shape, taste, color, smell, or feel? Is your medicine packaged differently? Is it still giving you the same result?

- Check containers for broken seals or changes in the label. If you think it's counterfeit, contact the pharmacy where you bought the medicine, and talk to your doctor. Also, notify the Food & Drug Administration at (800) FDA-1088 or go to http://www.fda.gov/cder/consumerinfo/counterfeit_text.htm.

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September 2007

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CALIFORNIA STATE
BOARD OF PHARMACY

BE AWARE & TAKE CARE:
Talk to your pharmacist!

Traveling Medicine Chest

Before you leave home for vacation or business, it may be helpful to pack the following items and take them with you on your trip. Planning ahead may prevent your trip from being ruined by minor illnesses. Talk to your doctor or pharmacist if you have any questions about over-the-counter medications and prescription drugs.

- Tylenol, Advil, or Motrin (for pain relief)
- Pepto Bismol, Kaopectate, or Imodium (for diarrhea)
- Maalox or Gaviscon (as antacid)
- Senokot or Milk of Magnesia (for diarrhea)
- Meclizine (for motion sickness)
- 1% hydrocortisone cream (for rashes or insect bites)
- Claritin or Chlor Trimeton (for allergies)
- Sudafed (as decongestant)
- Mucinex D (for cough and congestion)
- Neosporin or Bacitracin and Band-Aids (for cuts and scrapes)
- Artificial Tears (for eyes)
- Sunscreen
- Multivitamins
- Prescription drugs normally taken, in their original labeled containers (this is important if you need to have medicine refilled while away from home)

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September 2007

DRAFT 9/7/07

CALIFORNIA STATE BOARD OF PHARMACY

BE AWARE & TAKE CARE:
Talk to your pharmacist!

Vaccinations and Travel Outside the United States

If you travel outside the United States, plan ahead for vaccinations you may need before you leave on your trip. The Department of Health & Human Services Centers For Disease Control and Prevention has a list of worldwide destinations and health information for each country. See http://wwwn.cdc.gov/travel/destinationList.aspx for important information regarding vaccines and vaccine-preventable diseases.

You can also get information from professional medication organizations that provide directories of private travel clinics throughout the United States. See the International Society of Travel Medicine Clinic Directory at http://www.istm.org/ or the American Society of Tropical Medicine and Hygiene at http://www.astmh.org/ to locate health care professionals with an expertise in travel medicine.

- Schedule a visit to your doctor or travel medicine provider four to six weeks before your trip – most vaccines take time to become effective in your body and some vaccines must be given in a series over a period of days or sometimes weeks

- Ask your doctor about "routine" vaccinations, "recommended" vaccinations, and "required" vaccinations – what you need depends on your destination, whether you will spend time in rural areas, the season of the year you will travel, your age, health status, and previous immunizations

- Be aware that vaccine prices vary, and some vaccines will require more than one dose – the Hepatitis A vaccine requires 2 doses, the Hepatitis B vaccine requires 3 doses, and the Rabies vaccine requires 3 doses

California State Board of Pharmacy
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ugust 2007

Agenda Item 4

Update on a Proposed Forum on Medicare Part D Plans

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: September 7, 2007

To: Members, Communication & Public Education Committee

Subject: Forum on Medicare Part D

Since late 2005, the board has been working with various stakeholder groups to aid patients in receiving benefits under the federal Medicare Modernization Act, and specifically the Medicare Part D plans, that were implemented in January 2006.

The board has held six public forums over the last one and one-half years to discuss difficulties patients and providers are having with the plans, in hopes of finding resolutions. However, any structural changes to the program need to be made at the federal level.

At the April Board Meeting, the board directed staff to seek a public forum, in conjunction with a member of the California Congressional Delegation, perhaps Pete Stark or Nancy Pelosi. The goal would be to discuss implementation issues impacting patient safety that warrant legislative correction .

Since the last board meeting, Congressman Pete Stark has been contacted (see following letter) and Board President Powers and I have had a telephone discussion with Mr. Stark.

The result was Congressman Stark's assessment that the White House would not make any modifications to the program, so holding a forum would not likely produce much. He encouraged the board to continue with its outreach activities, and to consider holding similar discussions with other state boards of pharmacy. A full report will be provided to the board in October.

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

July 26, 2007

The Honorable Fortney "Pete" Stark
US House of Representatives
39300 Civic Center Drive, Suite 220
Fremont CA 94538

Sent via fax to: 510-494-5854

Congressmember Stark:

We are aware of your interest and leadership in the implementation of the Medicare Modernization Act. In this capacity, we are writing to ask for your participation in a meeting with various California constituents on unresolved issues at time of your choice in the future.

For nearly two years, the California State Board of Pharmacy has watched the implementation of the Medicare Part D Prescription Drug benefits. During this period, the board has held six public forums encouraging problem solving and patient advocacy.

As the regulator of pharmacists and pharmacies in California and coupled with the board's mandate to protect the safety of consumers, the board is uniquely situated to hear the problems. The board agrees with the general consensus that patients are benefiting from the Part D prescription drug program. However, the board believes that additional problems remain that vitally need to be resolved.

The lack of resolution of these problems imperil the health of affected patients, often dual eligibles, skilled nursing patients and critically ill patients being discharged from hospitals who need specialized care. While the problems affect the health of Californians, the board is unable to effect resolutions because of the structure of this Medicare benefit.

The board recognizes that to resolve many of these problems, a federal legislative solution is needed. For this reason, we are requesting your participation in developing a solution.

We are interested in convening a meeting in California with the staff of the California Department of Health Care Services, California health care plans, patient advocates and health care providers, specifically pharmacies, for discussion and possible

resolution of components that prevent patients from receiving necessary, timely and mandated care.

For example, some of the problems the board is aware of include:

1) Prior authorization requirements that delay patient drug therapy – patients must wait days for approval of the prior authorization process initiated from the prescriber's office unless the pharmacy is willing to risk providing medicine without knowing whether it will be ultimately covered.
2) Unacceptable sales tactics used by insurance agents selling Medicare plans; for example, dual eligibles being targeted for sales of private fee-for-service plans that their physicians will not accept.
3) Patients who are enrolled in a plan but whose coverage in the plan has not yet been activated are unable to obtain their medicine.
4) The Part D benefit is too complex to enable true comparison shopping by patients of the 55 competing plans in California. The number of plans and lack of standardization of benefits make it difficult to select plans that work for a patient, much less select the best plan for him or herself.
5) It is difficult for patients to resolve problems with their Part D benefit. Part D, Medicare Advantage and CMS call centers do not always give accurate and complete responses needed to resolve problems, leaving patients without adequate resolutions.
6) There are co-pay problems in skilled nursing facilities, where patients are told to make copayments.
7) Plans change formularies after a patient selects a plan, creating coverage problems for the patient who selected a plan expecting coverage for a specific drug.
8) Poor continuity of care when a patient is discharged from an acute hospital on "non-covered" drugs, impacting the patient's drug therapy and health.
9) Poor understanding of IV product/coverage/billing by plans (and therefore determining such services are "not covered" with the resultant care problems for patients, or continued hospitalization until the coverage is secured).
10) Poor "timely" response by plans to the pharmacy when the law requires in a skilled nursing facility a 1-hour or 4-hour delivery of medication under Title XXII
11) Requirements that physicians must do prior authorizations (not allowing the pharmacist to do this, which further delays therapy for patients, and redirects pharmacies to additional phone calls, away from other care functions).
12) Drugs on plan formularies that are "not geriatric friendly" per federal and state regulations and guidelines.
13) According to an article in the *American Journal of Psychiatry*, 30 percent of dual eligible beneficiaries were denied medication refills and 22 percent had interrupted or discontinued access to medicine; these difficulties led to suicide, hospitalizations and homelessness.

The board is willing to schedule and host a meeting at your convenience and at a location of your choice in California so that interested stakeholders could have the opportunity to provide these concerns directly to you.

The board strongly hopes for changes that will remove barriers that prevent patients from getting the medicine they are entitle to under the Medicare Modernization Plan.

Please advise us if you or your staff would be willing to discuss details for such a meeting in California. To make arrangements or if you have questions, please do not hesitate to contact the board's Executive Officer Virginia Herold (916-574-7911).

Thank you for your consideration of this proposal.

Sincerely,

William Powers

William Powers
President
California State Board of Pharmacy

Agenda Item 5

Medication Compliance

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: September 7, 2007

To: Members, Communication and Public Education Committee

Subject: Medication Compliance

Five items are provided for the Communication and Public Education Committee relating to medication compliance as follows:

1. Enhancing Prescription Medicine Adherence: A National Action Plan

   This publication from the National Council on Patient Information and Education (NCPIE) is dated August 2007. This publication identifies action steps that can significantly impact medication adherence.

2. 'Take as Directed' a lot easier with these new tools

   This article from DrugTopics.com dated August 20, 2007 looks at new ways to increase medication compliance.

3. America's Other Drug Problem, Poor Medication Adherence

   This article from PharmacyFoundation.org dated August 1, 2007 references the NCPIE report, and looks at ways to increase medication adherence.

4. Millions of Patients Not Taking Prescription Drugs Properly, Report Says

   This article posted on kaisernetwork.org references the NCPIE report and other articles in the media relating to medication compliance.

5. Medication Adherence

   This print out from *Pharmacist's Letter* dated August 2007 relates to medication adherence.

EDUCATE *before* YOU MEDICATE

The NCPIE Coalition–working together to promote safe medicine use

Enhancing Prescription Medicine Adherence:
A National Action Plan

National Council on Patient Information and Education

August 2007

National Council on Patient Information and Education
4915 Saint Elmo Avenue
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Bethesda, MD 20814-6082
301-656-8565

Printed in the United States of America.

Preface

In the United States and around the world, there is compelling evidence that patients are not taking their medicines as prescribed, resulting in significant consequences. Lack of medication adherence is *America's other drug problem* and leads to unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and even death.

Contributing to *America's other drug problem* are numerous behavioral, social, economic, medical, and policy-related factors that must be addressed if medication adherence rates are to improve. This includes lack of awareness among clinicians about basic adherence management principles, poor communication between patients and clinicians, operational aspects of pharmacy and medical practice, and professional barriers. Moreover, adherence improvement is affected by federal policies that provide insufficient funding for adherence-related research and federal and state laws and regulations that impact the availability of compliance assistance programs. All of these problems contribute to a rising tide of poor medication adherence and all must be addressed.

The ramifications of poor prescription medicine adherence affect virtually every aspect of the health care system. Addressing this persistent and pervasive problem cannot wait. Today, extensive research data exist that point to actions that can be taken now to improve adherence education and medication management. Accordingly, the National Council on Patient Information and Education (NCPIE) -- a non-profit coalition of more than 100 organizations that are working to stimulate and improve communication on the appropriate use of medicines -- convened a group of advisors from leading professional societies, voluntary health organizations, and patient advocacy groups to assess the extent and nature of poor medicine adherence, its health and economic costs, and its underlying factors. These advisors also examined the current state of research funding and educational initiatives around patient adherence to determine where major gaps still exist.

What follows is the result of this review, which focuses specifically on identifying those action steps that can significantly impact medication adherence and can be readily implemented. As such, this report serves as a **blueprint for action** by all stakeholders. To achieve the awareness, behavior changes, and additional resources for research and education that will improve patient medication adherence requires an ongoing partnership through which policymakers, regulators, the public health community, clinicians, the pharmaceutical industry, and patient advocates can share research, resources, and good ideas, while working toward a common goal. It is intended that this report will be a catalyst for this necessary and important collaborative effort.

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Executive Summary

At the same time that medical science has made possible new therapies for treating AIDS, cancer, and other once fatal diseases, poor adherence with medication regimens has reached crisis proportions in the United States and around the world.

On a worldwide basis, the World Health Organization (WHO) projects that only about 50 percent of patients typically take their medicines as prescribed. In the U.S., non-adherence affects Americans of all ages, both genders and is just as likely to involve higher-income, well-educated people as those at lower socioeconomic levels. Furthermore, since lack of medication adherence leads to unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and even premature death, poor adherence has been estimated to cost approximately $177 billion annually in total direct and indirect health care costs.

Although the challenge of poor medication adherence has been discussed and debated for at least three decades, these problems have generally been overlooked as a serious public health issue and, as a result, have received little direct, systematic, or sustained intervention. As a consequence, Americans have inadequate knowledge about the significance of medication adherence as a critical element of their improved health. Further, adherence rates suffer from the fragmented approach by which hospitals, health care providers, and other parts of the health delivery system intervene with patients and caregivers to encourage adherence. Consequently, many leading medical societies are now advocating a multidisciplinary approach through coordinated action by health professionals, researchers, health planners and policymakers.

Over a decade ago, the National Council on Patient Information and Education (NCPIE) recognized the need for such a coordinated approach to improved medication adherence and issued a report -- *Prescription Medicine Compliance: A Review of the Baseline Knowledge* -- which defined the key factors contributing to poor adherence. Since that time, the National Institutes of Health (NIH) and a number of voluntary health organizations in the U.S. have weighed in with new findings on the importance of adherence for successful treatment. Further elevating the need for action is the WHO, which has called for an initiative to improve worldwide rates of adherence to therapies commonly used in treating chronic conditions, including asthma, diabetes, and hypertension.

Unfortunately, however, these calls for action have yet to be heeded and rates of medicine adherence have not improved. Thus, action is needed now to reduce the adverse health and economic consequences associated with this pervasive problem. While no single strategy will guarantee that patients will fill their prescriptions and take their medicines as prescribed, elevating adherence as a priority issue and promoting best practices, behaviors, and technologies may significantly improve medication adherence in the U.S.

Towards this end, NCPIE convened a panel of experts to create consensus on ten national priorities that may have the greatest impact on improving the state of patient adherence in the U.S. These recommendations serve as a catalyst for action across the continuum of care -- from diagnosis through treatment and follow-up patient care and monitoring. Ultimately involving the support and active participation of many stakeholders -- the federal government, state and local government agencies, professional societies and health care practitioners, health educators, and patient advocates -- this platform calls for action in the following areas:

1. **Elevate patient adherence as a critical health care issue.**
   Medication non-adherence is a problem that applies to all chronic disease states;

affects all demographic and socio-economic strata; diminishes the ability to treat diabetes, heart disease, cancer, asthma, and many other diseases; and results in suffering, sub-optimal utilization of health care resources, and even death. Despite this impact, patient adherence is not on the radar screen of policy makers and many health professionals, which has meant inconsistent government policies and a lack of resources for research, education, and professional development. Until health care policy makers, practitioners and other stakeholders recognize the extent of non-adherence, its cost, and its contribution to negative health outcomes, this problem will not be solved.

2. **Agree on a common adherence terminology that will unite all stakeholders.**
   Today, a number of common terms -- compliance, adherence, persistence, and concordance -- are used to define the act of seeking medical attention, filling prescriptions and taking medicines appropriately. Because these terms reflect different views about the relationship between the patient and the health care provider, confusion about the language used to describe a patient's medication-taking behavior impedes an informed discussion about compliance issues. Therefore, the public health community should endeavor to reach agreement on standard terminology that will unite stakeholders around the common goal of improving the self-administration of treatments to promote better health outcomes.

3. **Create a public/private partnership to mount a unified national education campaign to make patient adherence a national health priority.**
   To motivate patients and practitioners to take steps to improve medication adherence, compelling, actionable messages must be communicated as part of a unified and sustained public education campaign. A foremost priority is creating the means by which government agencies, professional societies, non-profit consumer groups, and other affected stakeholders can work together to reach public and professional audiences on a sustained basis. Even as NCPIE and various government agencies, professional societies, and voluntary health organizations work to provide information about medication adherence, there needs to be a national clearinghouse, serving as the catalyst and convener so that all stakeholders can speak with one voice about the need for improving patient adherence. NCPIE, a professional society, or academic institution could manage this clearinghouse effectively.

4. **Establish a multidisciplinary approach to adherence education and management.**
   There is a growing recognition that a multidisciplinary approach to medication taking behavior is necessary for patient adherence to be sustained. This has led NCPIE to promote a new model -- the "Medicine Education Team" -- in which the patient and all members of the health care team work together to treat the patient's condition, while recognizing the patient's key role at the center of the process. Looking to the future, this approach has potential to improve adherence rates significantly by changing the interaction between patients and clinicians and by engaging all parties throughout the continuum of care.

5. **Immediately implement professional training and increase the funding for professional education on patient medication adherence.**
   Today's practitioners need hands-on information about adherence management to use in real-world settings. This need comes at a time when a solid base of research already exists about the steps physicians and other prescribers, pharmacists, nurses, and other health care practitioners can take to help patients improve their medication taking behavior.

Professional societies and recognized medical sub-specialty organizations should immediately apply these research findings into professional education through continuing education courses as well as lecture series on patient adherence issues.

6. **Address the barriers to patient adherence for patients with low health literacy.**
Low health literacy and limited English proficiency are major barriers to adherence and deserve special consideration. Thus, an important target for patient-tailored interventions is the 90 million Americans who have difficulty reading, understanding and acting upon health information. Accordingly, advocates recommend widespread adoption of existing tools, such as the Rapid Estimate of Adult Literacy in Medicine Revised (REALM-R), validated pictograms designed to convey medicine instructions and specific patient education programs that promote and validate effective oral communication between health care providers and patients supported by provision of adjunctive, useful information in its most useful format to address the patient's individual capabilities.

7. **Create the means to share information about best practices in adherence education and management.**
Today, stakeholders have access to more than 30 years of research measuring the outcomes and value of adherence interventions. Building on this foundation, a critical next step is for the federal government -- through the Adherence Research Network -- to begin collecting data on best practices in the assessment of patient readiness, medication management and adherence interventions, incentives that produce quality outcomes from adherence interventions, and measurement tools so that this information can be quantified and shared across specialties and health care facilities. Just as federal and state registries collect and share necessary data on different disease states, a shared knowledge base regarding systems change, new technologies, and model programs for evaluating and educating patients about adherence will significantly improve the standard of adherence education and management.

8. **Develop a curriculum on medication adherence for use in medical schools and allied health care institutions.**
Lack of awareness among clinicians about basic adherence management principles and their effective application remains a major reason that adherence has not advanced in this country. Changing this situation will require institutionalizing curricula at medical, nursing, pharmacy, and dental schools as well as courses for faculty members that focus on adherence advancement and execution of medication-related problem solving. Moreover, once these courses are developed, it will be important for academic centers to elevate patient adherence as a core competency by mandating that course work in this area be a requirement for graduation.

9. **Seek regulatory changes to remove road-blocks for adherence assistance programs.**
Improved adherence to medication regimens is predicated in part on supportive government policies. Unfortunately, a number of federal and state laws and policies now limit the availability of adherence assistance programs. Accordingly, limitations to patient communication about medicine adherence in federal and state laws must be identified for lawmakers and regulators to resolve. Key issues to be addressed include clarifying that education and refill reminder communications fall within the scope of the federal anti-kickback statute, and ensuring that federal and state laws related to patient privacy and the use of prescription data are in balance such that they do not unduly limit the ability of pharmacies to communicate with patients about the

importance of adhering to their prescribed therapy.

10. **Increase the federal budget and stimulate rigorous research on medication adherence.**
Although the National Institutes of Health created the Adherence Research Network to identify research opportunities at its 18 Institutes and Centers, the Network has been inactive since 2002. Moreover, in 2000, when the Network was funding adherence research, the actual NIH dollars earmarked for testing interventions to improve medication-taking behavior was only $3 million in a budget of nearly $18 billion. Thus, it will be important for stakeholders to advocate for the Adherence Research Network to be re-invigorated and for NIH to significantly increase the proportion of its research funding to test adherence interventions and measure their effectiveness. Even if NIH triples its 2000 commitment, the small amount spent on patient adherence will still signal that the issue is a critical area for new research efforts.

*****

Everyone in the health care system – from patients and caregivers to health care providers, patient advocates and payors – has a significant role to play in improving prescription medicine adherence. Thus, an agenda that removes the barriers and advances education and information sharing is a critical step to improving the health status of all Americans. Clearly, the time for action is now.

Introduction

There is much to celebrate about the improved health status of many Americans. Smoking rates have dropped significantly, infant mortality has declined and there have been major advancements in treatments for serious diseases that once devastated the lives of millions. This includes more than 300 new drugs, biologics and vaccines approved by the U.S. Food and Drug Administration (FDA) since 1993 to prevent and treat over 150 medical conditions.[1]

While we recognize such progress, now is the time to be even more mindful of the public health problems we have yet to solve. One of these persistent challenges is improving patient "compliance" (or "adherence") – defined as the extent to which patients take medications as prescribed by their health care providers.[2] At the same time that medical science has made possible new therapies for treating AIDS, cancer, and other once fatal diseases, poor adherence with medication regimens has reached crisis proportions in the United States and around the world. According to the World Health Organization (WHO), only about 50 percent of patients typically take their medicines as prescribed.[3] For this reason, WHO calls poor adherence rates "a worldwide problem of striking magnitude"[3] and has published an evidence-based guide for health care providers, health care managers, and policymakers to improve strategies of medication adherence.[2]

Looking specifically at lack of medication adherence in the U.S., a recent survey reported that nearly three out of every four American consumers report not always taking their prescription medicine as directed.[4] Commissioned by the National Community Pharmacists Association (NCPA), this survey also found a major disconnect between consumers' beliefs and their behaviors when it comes to taking medicines correctly. Some of the findings of the survey include:

+ Almost half of those polled (49 percent) said they had forgotten to take a prescribed medicine;
+ Nearly one-third (31 percent) had not filled a prescription they were given;
+ Nearly three out of 10 (29 percent) had stopped taking a medicine before the supply ran out; and
+ Almost one-quarter (24 percent) had taken less than the recommended dosage.

While disturbing, these statistics only begin to demonstrate the magnitude and scope of poor adherence in the U.S. Lack of adherence affects Americans of all ages and both genders, but is of particular concern among those aged 65 and over who, because they have more long-term, chronic illnesses, now buy 30 percent of all prescription medicines[5] and often combine multiple medications over the course of a day. Regardless of age and sex, poor medication adherence is also just as likely to involve higher-income, well-educated people as those at lower socioeconomic levels.[2] As a result, poor medication adherence has been estimated to cost approximately $177 billion annually in total direct and indirect health care costs.[6]

Adherence rates are typically higher in patients with acute conditions, as compared to those with chronic conditions, with adherence dropping most dramatically after the first six months of therapy.[2] The problem is especially grave for such patients with chronic conditions requiring long-term or lifelong therapy, because poor medication adherence leads to unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and premature death.[3] Lack of adherence also increases the risk of developing a resistance to needed therapies (e.g., with antibiotic therapy), more intense relapses, and withdrawal (e.g., with thyroid hormone replacement therapy)

and rebound effects (e.g., with hypertension and depression therapy) when medication is interrupted.[3] Because of this impact, adherence has been called "the key mediator between medical practice and patient outcomes."[7]

A TIME FOR ACTION

Although the challenge of poor medication adherence has been discussed and debated for at least three decades, these problems have generally been overlooked as a major health care priority. Compounding the situation, adherence problems have been exacerbated by the fragmented approach by which hospitals, health care providers, and other parts of the health delivery system intervene with patients and caregivers to encourage adherence. Consequently, many leading medical societies are now advocating a multidisciplinary approach through coordinated action by health professionals, researchers, health planners and policymakers.

Over a decade ago, the National Council on Patient Information and Education (NCPIE) recognized the need for such a coordinated approach to improved medication adherence and issued a report -- *Prescription Medicine Compliance: A Review of the Baseline Knowledge*[8] -- which defined the key factors contributing to poor adherence. The report further outlined strategies that could be implemented by health care professionals, patients and caregivers and health care systems, including these key strategies recommended for health care providers:

- Using a verbal discussion reinforced with appropriately designed written materials to help the patient understand the medical condition, the need for the treatment, and the value of the treatment;
- Offering verbal counseling from both the prescribing health care provider and the pharmacist that the prescription should be filled and taken as prescribed. While written instruction sheets can reinforce these instructions, they should never be used as a substitute for counseling;
- Providing useful written information in "patient language" that clearly explains how the patient can correctly manage his/her medications. This information includes details on how to administer the medication, the exact time the medicine should be taken and why, how long to take the medicine, recognition and management steps for common side effects, special precautions, and how to monitor the progress of the therapy;
- Making patients aware of the various medication adherence aids and devices available, such as dosing reminders, pill boxes and refill reminder programs;
- Monitoring patient adherence with every visit to the prescribing health care provider or pharmacist; and
- Instructing patients and caregivers on home monitoring activities (such as home blood pressure monitoring) and home monitoring records that should be maintained for use during future medical and pharmacy visits.

Since the NCPIE report was published, the National Institutes of Health (NIH) and a number of voluntary health organizations focusing on the major chronic diseases affecting Americans today -- asthma, cancer, cardiovascular disease, diabetes and mental illness -- have weighed in with new findings on the importance of adherence for successful treatment. The consensus of these groups is that interventions that improve patient adherence improve health status and reduce health care costs. As stated in *The Multilevel Compliance Challenge*, a paper by the American Heart Association:

> "Maximum use of strategies to enhance compliance must be made. Application of these strategies is particularly important now, when there is great pressure to decrease costs and improve quality and patient outcomes."[9]

Further elevating the need for action is the World Health Organization (WHO), which has called for an initiative to improve worldwide rates of adherence to therapies commonly used in treating chronic conditions, including asthma, diabetes, and hypertension. In a 2003 report entitled *Adherence*

to Long-Term Therapies: Evidence for Action, WHO defined poor medication adherence as a critical issue for global public health, and identified five broad dimensions affecting adherence that need to be addressed by health managers and policymakers:[3]

1. social and economic factors;
2. health system and health care team-related factors;
3. therapy-related factors;
4. condition-related factors; and
5. patient-related factors.

To bring about needed change, the WHO report called for a multidisciplinary approach toward adherence that includes patient-tailored interventions and training in adherence management for health professionals. This approach was also addressed in a 2005 review article by researchers Lars Osterberg, M.D., and Terrence Blaschke, M.D. published in the *New England Journal of Medicine* where the authors identified 12 major predictors associated with poor adherence -- from the side effects of treatment to the patient's belief in the benefit of the medicine.[2] (See Table 1; page 29) Noting that race, sex, and socioeconomic status have not been consistently associated with levels of adherence,[2] the authors conclude that poor adherence should always be considered when a patient's condition is not responding to therapy. Accordingly, the authors recommend that physicians ask a series of non-judgmental questions of their patients designed to facilitate the identification of poor adherence and enlist ancillary health care providers, such as pharmacists, behavioral specialists, and nursing staff to improve adherence.[2]

Another major development since the publication of NCPIE's report is new technology that makes available a number of useful mechanisms for fostering adherence. For example, patients can receive pharmaceutical information and refill reminders via letter, fax, telephone, e-mail and pager messages. There are also electronic reminder devices, which can be programmed for multiple daily alarms and may permit the user to record brief dosing instructions. Moreover, a number of medication organizers now incorporate electronic alarms to alert patients when doses are due.

Despite such developments, adherence rates have not changed significantly since NCPIE issued its recommendations over a decade ago, demonstrating that an intensified, sustained focus on adherence improvement among all stakeholders is essential to reduce the adverse health and economic consequences associated with this pervasive problem. While no single strategy will guarantee that patients will fill their prescriptions and take their medicines as prescribed, elevating adherence as a priority issue and promoting best practices, behaviors, and technologies may significantly improve medication adherence in the U.S.

This report, therefore, is intended as a renewed nationwide call to action. Based on an analysis of research to date, it examines the current state of patient adherence and trends that may lead to improved medication use. This report also offers realistic goals for improving medication adherence through patient information and education, health professional intervention, and supportive government policies.

Prescription Medicine Adherence:
A Fresh Look at a Persistent and Complex Problem

Even as the issue of taking medicines as prescribed is getting increased attention within the public health community, the multi-faceted nature of poor adherence has significantly clouded the debate. The following is a look at the current state of patient adherence and the factors contributing to this complex problem.

LACK OF A STANDARD DEFINITION AND CONSISTENT TERMINOLOGY LIMITS CONSENSUS

Even though there is a growing recognition about the need for improvements in medication adherence, progress has been hampered by a lack of consistent terminology. Today, a number of common terms are used to define the act of seeking medical attention, filling prescriptions, and taking medicines appropriately. All have their supporters and detractors and all reflect different views about the relationship between the patient and the health care provider.

In its 1995 report, NCPIE defined adherence as following a medicine treatment plan developed and agreed on by the patient and his/her health professional(s). Originally, NCPIE used the term "compliance" because historically, it is the term most widely used in medical indices. First appearing in the medical literature in the 1950's, the term "compliance" came into popular use following the 1976 publication of the proceedings of the first major academic symposium on the subject.[10] As originally defined, "compliance" was intended to describe "the extent to which patients' behaviors coincide with the health care providers' medical or health advice."

Yet to many researchers, "compliance" connotes a passive role for the patient and appears to blame and stigmatizes the patient's independent judgment as deviant behavior. Thus, many stakeholders prefer the term "adherence," which implies a more collaborative relationship between patients and clinicians and is more respectful of the role that patients can play in their own treatment decisions. Thus, the NCPIE definition proposed in 1995 was intended to encompass the concept of adherence, including two-way communication, patient-centered treatment planning, and agreement upon the medication and dosing requirements.

The term "persistence" has also entered the lexicon and is intended to address the treatment continuum, beginning with having the prescription filled and continuing with taking and refilling the medicine for as long as necessary. However, in the view of some researchers, the term "adherence" is more comprehensive and reflects both taking the medicine as directed (compliance) and continuing to take the medication for the duration required (persistence).

Another term now being used is "concordance," which is intended to convey an active partnership between the patient and the health care professional. Developed by the Royal Pharmaceutical Society of Great Britain, the concept suggests that the clinician and patient find areas of health belief that are shared and then build on these beliefs to improve patient outcomes.[11] However, this term has also been challenged as being more inspirational than what is possible in promoting better medication taking by patients.

Despite the increased use of "persistence," and "concordance," many researchers now use the terms "compliance" and "adherence" interchangeably. However, since "concordance" is being increasingly used in Europe, an important priority for the global public health community is to agree on a standard definition that will unite all stakeholders around the common goal of improving the self-administration of treatments to promote better health outcomes. For the purposes of this report, NCPIE has adopted

the term "adherence" because the term supports a patient-centered approach to improving how patients seek information, fill their prescriptions and take their medicines as prescribed.

THE EXTENT OF THE PROBLEM

Agreeing on a standard definition for patient adherence also requires an up-to-date assessment of the problem, which today rivals many disease states in terms of prevalence, human suffering, and health care costs. From a public health perspective, poor adherence is nothing short of a crisis.

Although the problem varies by condition and the types of drugs prescribed, it is significant, not only in the U.S. but around the world. According to research findings:

- Between 12 percent and 20 percent of patients take other people's medicines;[11]
- In developed countries like the U.S., adherence among patients with chronic conditions averages only 50 percent;[3]
- Other studies show that about one-third of patients fully comply with recommended treatment while another third sometimes comply and one-third never comply;[12]
- The World Health Organization reports that only about 43 percent of patients in developed nations take their medicines as prescribed to treat asthma and between 40 percent and 70 percent follow the doctor's orders to treat depression;[3]
- Although hypertension increases the risk of ischemic heart disease three- to four-fold and increases the overall cardiovascular risk by two- to three-fold, just 51 percent of patients take their prescribed doses of drugs to manage this condition;[13]
- Among 17,000 U.S. patients prescribed beta blocker drugs following a heart attack, a major study conducted by Duke University Medical Center reported that only 45 percent regularly took these medications during the first year after leaving the hospital, with the biggest drop in adherence occurring during the initial months after hospital discharge;[13]
- Less than 2 percent of adults with diabetes perform the full level of care, which includes self-monitoring of blood glucose and dietary restrictions as well as medication use, that is recommended by the American Diabetes Association;[14]
- Although adherence with short-term therapy is generally considered to be higher than for long-term treatments, rapid declines occur even in the first ten days of use;[15] and
- Even among health care professionals, self-reported adherence with prescribed therapies averaged only 79 percent in one study.[16]

Researchers have found that even the potential for serious harm may not be enough to motivate patients to take their medicines appropriately. In one study, only 42 percent of glaucoma patients met minimal criteria for adherence after having been told they would go blind if they did not comply. Among patients who already had gone blind in one eye, adherence rates rose only to 58 percent.[17] Another study of renal transplant patients facing organ rejection or even death from poor adherence with immunosuppressant therapy found that 18 percent of patients were not taking their medicine as prescribed.[18]

SPECIAL POPULATIONS AT RISK

Of special concern to the public health community is poor adherence among people aged 65 and over, who tend to have more long-term, chronic illnesses--such as arthritis, diabetes, high blood pressure, and heart disease-- and therefore, take more different medications as they age. According to one study, people aged 75 years and older take an average of 7.9 drugs per day.[11] Other studies have shown that between 40 percent and 75 percent of older people do not take their medications at the right time or in the right amount[19] due to such complicating factors as having multiple health problems requiring treatment,

needing multiple medications, being seen by multiple prescribers, and having physical and cognitive challenges that may impact medication use.

The impact of poor adherence is also a serious problem among the medically underserved -- those Americans of all ethnic backgrounds who are poor, lack health insurance, or otherwise have inadequate access to high-quality health care. According to the third National Healthcare Disparities Report (NHDR) issued in 2005 by the Agency for Healthcare Research and Quality (AHRQ), health care disparities by race and ethnicity remain prevalent in the U.S. and are significantly correlated with health literacy -- the ability of an individual to access, understand and use health-related information and services to make appropriate health decisions -- among the underserved. The Office of the U.S. Surgeon General estimates that more than 90 million Americans cannot understand basic health information,[20] which costs the health system billions of dollars each year due to misdirected or misunderstood medical advice.

Children and teenagers are also an at-risk group, especially when it comes to adherence to treatments for asthma, one of the most common chronic diseases of childhood.[21] Research shows that adherence to prescribed pulmonary medication may be as low as 30 percent in adolescents,[3] leading to uncontrolled asthma. A number of factors related to children's experiences taking medicines during their formative years affect future rates of compliance. These factors include parents not adequately monitoring their children's use of medicines, poor parental adherence to treatment regimens, and lack of school education about medicine use.

PAYING THE PRICE FOR POOR ADHERENCE

Who is paying the price for the epidemic of poor medication adherence? We all are -- and the costs are substantial. Researchers have calculated that non-adherence costs the U.S. health care system about $100 billion annually,[22, 23, 24] including approximately $47 billion each year for drug-related hospitalizations.[25] Moreover, not taking medicines as prescribed has been associated with as many as 40 percent of admissions to nursing homes[26] and with an additional $2,000 a year per patient in medical costs for visits to physicians' offices.[26] The total direct and indirect costs to U.S. society from prescription drug non-adherence are about $177 billion annually.[27]

Employers also pay a high price for employees' non-adherence to prescribed medical treatments, both in terms of reduced productivity and absenteeism, and in higher costs for private or managed care health insurance benefits. With prescription drugs representing the fastest-growing cost component for most health plans (climbing at more than 17 percent annually),[28] employers are increasingly requiring that covered members and their families assume a greater percent of their cost.

Although the economic cost associated with poor adherence is already staggeringly high, the World Health Organization predicts that this problem will only grow as the burden of chronic diseases increases worldwide.[3] As policymakers consider ways to address the escalating costs of health care in the U.S., it is critical that the agenda include the pressing issue of improving patient adherence with medication regimens. Mounting evidence shows that better adherence leads to improved clinical outcomes and reduced costs.[29] Based on a meta-analysis of 63 studies involving more than 19,000 patients, higher adherence was found to reduce the risk for a poor treatment outcome by 26 percent.[30] Other data associate patient self-management and adherence programs with a reduction in the number of patients being hospitalized, days in the hospital, and outpatient visits. The data suggest a cost to savings ratio of approximately 1:10 in some cases, with the results continuing over several years.[31]

As Americans age, an increasing number are prescribed multiple medications for multiple chronic conditions. As a result, new strategies to enhance prescription medicine adherence are needed. While new interventions are not cost-free, improving adherence is likely to increase the cost effectiveness of health interventions, thereby reducing the burden of chronic illness. The investment of time and resources to improve patient adherence will likely more than pay for itself through improved health status and reduced utilization and costs.

What Is Behind Poor Adherence:
Factors That Contribute to the Problem

Poor adherence encompasses much more than patients not taking their medicines as directed. Numerous behavioral, social, economic, medical, and policy-related factors contribute to the problem and must be addressed if adherence rates are to improve.[3]

To understand the interplay of these issues, the research community has categorized the factors underlying non-adherence as medication-related, patient-related, prescriber-related, and pharmacy-related. Additionally, federal and state government policies can also serve as impediments to adherence improvement. The following describes these factors and the challenges they represent.

MEDICATION-RELATED FACTORS

For many patients, one of the biggest stumbling blocks to taking their medicines is the complexity of the regimen. Studies find that patients on once-daily regimens are much more likely to comply than patients who are required to take their medicine(s) multiple times each day.[32]

Conversely, the number of medications a person takes has a negative impact on adherence. In any given week, four out of five U.S. adults will use prescription medicines, over-the-counter (OTC) drugs, or dietary and herbal supplements and nearly one-third will take five or more different medications.[33] Of special concern are adults aged 65 and older, who take more prescription and OTC medicines than any other age group.[34] According to a 2001 survey of older Americans conducted by the American Society of Health-System Pharmacists (ASHP), 82 percent of patients over age 65 take at least one prescription medicine, more than half (54 percent) take three or four prescription medicines, and as many as a third (33 percent) take eight or more prescription medicines to treat their health conditions.[35] Adherence also decreases when patients are asked to master a specific technique in order to take their medication, such as using devices to test blood levels as part of a treatment protocol, using inhalers, or self-administering injections.[36]

Compounding the problem, many patients -- and especially older adults -- are being seen by more than one physician or other prescriber, and each may be prescribing medications for a specific condition. Unless there is a primary care provider who coordinates these medication regimens, the number of different medicines the patient takes each day may limit adherence while also increasing the risk of medication errors and harmful drug interactions.

Beyond the complexity of the regimen, concern about medication side effects remains a powerful barrier to patient adherence. In a 2005 survey of 2,507 adults conducted by Harris Interactive, nearly half of the respondents (45 percent) reported not taking their medicines due to concerns about side effects.[37] Conversely, when medications such as antidepressants and corticosteroids are slow to produce intended effects, patients may believe the medication is not working and discontinue use.[38]

Addressing these medication-related factors will require better communication between the patient and his/her prescriber about what to expect from treatment and about the patient's medication challenges (including the number of medicines being taken, worries about side effects and how to administer and monitor the medicine). Through high-quality, two-way discussions, clinicians will be able to identify and discontinue unnecessary medications, simplify dosing regimens, and address other medication-related issues that make adherence difficult.

PATIENT-RELATED FACTORS

Patients ultimately are in control of whether, how safely and how appropriately they take their

medicines. For example, a common reason why patients don't take their medicines is simply forgetfulness.[39] Another significant barrier is the inability to understand and act on instructions for taking the medication. In fact, a study found that 60 percent or more of patients being followed could not correctly report what their physicians told them about medication use 10 to 80 minutes after receiving the information.[40]

While problems such as these are significant, public health officials are increasingly concerned about patients and especially those with chronic conditions requiring long-term therapy, such as asthma, diabetes, and hypertension, who make a conscious choice not to fill the prescription, not to take their medicine as prescribed, or to discontinue therapy. Influencing these decisions are a number of factors related to the patient's experiences, perceptions, and understanding about his or her disease. These include:[41]

1. Perceptions about the nature and severity of their illness;
2. Denial of illness and the need to take medicines;
3. The assumption that once the symptoms improve or the person "feels better," he or she can discontinue use of the medication;
4. Limited appreciation about the value of medicines when properly used;
5. Beliefs about the effectiveness of the treatment;
6. Acceptance of taking medications for preventive purposes and for symptomless conditions (e.g. statins to lower blood cholesterol levels);
7. Worries about the social stigma associated with taking medicines;
8. Fear of side effects or concern about becoming drug dependent;
9. Fear of needles and the need for self-injections;
10. Lack of confidence in the ability to follow the medication regimen;
11. Media influence regarding safety or risk issues associated with particular medicines; and
12. Lack of positive motivations and incentives to make necessary changes in behavior.

Along with these attitudes and beliefs, the duration of the course of therapy also contributes to whether and how patients take their medicines.[36] Adherence rates have been found to decline over time when patients are treated for chronic conditions.[29]

Moreover, for many Americans, the high cost of medications is a barrier to medication use.[36] In a 2004 study of nearly 14,000 Medicare enrollees, 29 percent of disabled people and 13 percent of seniors reported skipping doses or not filling a prescription because of cost.[42] Limited access to health care services, lack of financial resources, and burdensome work schedules are also associated with poor adherence to medication regimens.[2]

Compounding these problems is the impact of low health literacy and limited English language proficiency, which greatly affect the ability of patients to read, understand, and act on health information about medication use. According to published studies, 45 percent of the adult population (90 million people) have literacy skills at or below the eighth grade reading level, making it difficult for these individuals to read health information, understand basic medical instructions and adhere to medication regimens.[43] In one study involving patients over age 60 who were treated at two public hospitals, 81 percent could not read or understand basic materials, such as prescription labels.[43] A 2006 study, published in the *Annals of Internal Medicine* found that low-literacy patients have difficulty understanding basic information regarding medication dosage. While over 70 percent of the respondents correctly stated instructions about taking two pills twice a day, only one-third (34.7 percent) could demonstrate the correct number of pills to be taken daily.[44]

Further, studies have found that people with low health literacy or limited English language proficiency are often ashamed to get help with medical instructions,[45] which increases the likelihood that they will not be able to follow their treatment regimens. As a result, the U.S. Surgeon General, the National Quality Forum, and other stakeholders have called for immediate action to improve adherence among these sizeable vulnerable populations.

PRESCRIBER-RELATED FACTORS

In 1995, NCPIE identified the lack of awareness of basic compliance management principles among some clinicians as a major causal factor for prescription non-adherence. More than a decade later, this appears to remain the case. According to a 2004 telephone survey conducted by the Food and Drug Administration (FDA), only 66 percent of consumers polled reported receiving instructions from their physician about how often to take a new medication and only 64 percent were told how much to take.[46] The survey also examined the receipt of medicine information at the pharmacy. Here, the figures dropped considerably, to 31 percent (how often to take) and 29 percent (how much to take) respectively.[46]

Why is this the case? One reason is that clinicians tend to overestimate the extent of their patients' ability to adhere to a medication regimen and the patient's actual adherence level. In one study of 10 family physicians who had known many of their patients for more than five years, researchers found that only 10 percent of the physicians' estimates of adherence with digoxin therapy were accurate when compared with information from a pill count and serum digoxin concentration measurements.[29] Earlier studies reported that health professionals overstate the adherence of their patients by as much as 50 percent.[47]

At the same time, the WHO report attributes lack of adequate medication counseling to the outdated belief that adherence is solely the patient's responsibility.[3] Practical issues such as lack of time and lack of financial reimbursement for education and counseling also represent persistent barriers to health care provider adherence interventions.[48]

Besides these practical issues is the factor of trust between the clinician and the patient. According to a study recently reported in the *Archives of Internal Medicine*, when physician trust levels are low, patients are more likely to forego the use of medications.[49] This study suggests that clinicians need to encourage adherence through behaviors designed to improve patient trust. Further, a meta-analysis of 21 studies assessing the quality of physician-patient communication found that the quality of communication both in the history-taking segment of the visit and during discussion of the management plan significantly improved patient health outcomes.[50]

Finally, there is the pervasive problem of poor communication between the clinician and the patient. Because this lack of effective communication can lead to medication errors and non-adherence, the Institute of Medicine (IOM) in its landmark 1999 report – *To Err is Human; Building a Safer Health System* – called on clinicians to educate their patients about the medications they are taking, why they are taking them, what the medications look like, what time patients should take their medicines, potential side effects, what to do if a patient experiences side effects, and what regular testing is necessary.[51] Osterberg and Blaschke also present a range of communications-based strategies for improving medication adherence in their review article, *Adherence to Medication*, published in the August 4, 2005 issue of the *New England Journal of Medicine*.[2] (See Table 2; page 30 of this report).

PHARMACY-RELATED FACTORS

Because pharmacists have direct and frequent contact both with prescribers and patients, research suggests that community-based pharmacists can play a unique role in promoting medication adherence.[3, 16] For example, a study examining the interaction of 78 ambulatory care clinical pharmacists with 523 patients treated at selected Veterans Affairs medical centers over the course of a year found that pharmacists were responsible

for adjusting patients' drug regimens as well as identifying and preventing drug-related problems.[52]

Also demonstrating the ability of community-based pharmacists to increase medication adherence is the recent Federal Study of Adherence to Medications in the Elderly (FAME) conducted among military health care beneficiaries aged 65 years or older who were prescribed at least four chronic medications a day. Designed to assess the efficacy of a comprehensive pharmacy care program, this multi-phase study examined the impact of patient education and the use of an adherence aid (medications custom packaged in blister packs), finding that the program increased medication adherence and persistence, whereas discontinuation of the program was associated with decreased medication adherence and persistence.[53] Findings from the FAME study call for greater emphasis within health care delivery systems and policy organizations on the development and promotion of clinical programs to enhance medication adherence particularly among the at-risk elderly population.

Despite these research findings, however, four categories of pharmacy-related barriers to improved patient adherence remain and must be addressed. Broadly defined, these categories are: the attitudes of patients and pharmacists, the knowledge level of pharmacists, the operational aspects of the pharmacy practice, and professional barriers.[41]

In its 1995 report, NCPIE identified many attitudinal barriers that contribute to the poor adherence, including the perceptions of patients, caregivers, and other health care providers about the expertise of pharmacists and the pharmacist's willingness to tailor education and counseling to the needs of the patient. Moreover, pharmacists' own views about their role in medication adherence can be a factor. Many pharmacists are accustomed to a paternalistic relationship where the pharmacist tells the patient what to do and the patient is expected to follow those instructions.[26] Further complicating the situation for pharmacists is identifying potential adherence problems when medication regimens can be complex and then applying complex technical information to practice situations.[26]

Beyond these issues, NCPIE has noted functional and professional barriers that can significantly impact the ability of pharmacists to engage in adherence education and counseling. Functional barriers can include space limitations, time constraints, the lack of resources, and the lack of management support to counsel patients on medication adherence.[55] Moreover, thousands of pharmacies must divert time and cannot efficiently fill prescriptions because information needed to obtain reimbursement frequently does not appear on a patient's drug benefit card. As a consequence, thousands of hours are occupied calling employers or insurance companies to obtain this information.[56] Reimbursement for counseling patients has not kept pace with the pharmacy profession's attempts to obtain this payment, although the Medicare prescription drug benefit plan affords opportunities due to requirements for medication therapy management programs (MTMP) for specific enrollees.

Professional barriers also arise from a lack of consensus within the pharmacy community about the role of pharmacists in health care delivery. To gain this consensus, national pharmacy organizations have endorsed the concept of "pharmaceutical care,"[57] a maturation of pharmacy as a clinical profession, with pharmacists cooperating directly with other professionals and the patient in designing, implementing and monitoring a therapeutic plan. This approach requires a knowledgeable frontline staff supported by managers, other pharmacists and effective work systems.

GOVERNMENT IMPEDIMENTS

The pharmaceutical care model advanced by the pharmacy community is predicated on supportive government policies. However, a number of federal and state laws, as currently interpreted, may actually impede the availability of adherence assistance programs.

One such impediment is the federal anti-kickback statute containing rules that cover businesses reimbursed by Medicare, Medicaid or other federally funded health care programs. This statute is so

broadly written that many types of health care practices and business relationships designed to increase patient adherence may theoretically be subject to criminal prosecution under the statute.

To help address this problem, the Office of the Inspector General (OIG) within the Department of Health and Human Services (HHS) issued regulations granting "safe harbor" protections to certain types of health care practices and business arrangements.[1] However, because OIG's regulations don't specifically cover patient education, medication refill reminder programs and other pharmacy-based adherence messaging programs, the result has been a reduced use of adherence messaging programs. In an abundance of caution, some refill reminder programs now exclude any patients who participate in any federal health care program (e.g., Medicare, Medicaid, TRICARE).[2]

Another impediment to pharmacy adherence assistance programs involves federal and state medical privacy requirements. At the federal level, there is the "Privacy Rule,"[3] a set of federal medical privacy regulations issued to implement the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Although these rules permit health care providers to carry out "treatment" functions, including refill reminders and other adherence messaging programs, without first obtaining the patient's written permission,[4] some privacy advocates object to these provisions.

With these concerns in mind, the National Consumers League (NCL) created voluntary performance-based Best Practice Principles that build on the requirements contained in the HIPAA privacy rule.[58] Developed by a Working Group of representatives from public interest groups, health professional societies, the consumer/privacy movement, pharmacy industry trade groups, pharmacy vendors, retail chains, and the pharmaceutical industry, the Best Practices Principles are intended to bridge the gap between the protections afforded by HIPAA and fair information practices that define the degree of control that consumers should have over the ways their health information is used. Accordingly, the Best Practices Principles include:[58]

+ Ensuring that a pharmacy's Notice of Privacy Practices can be easily understood;
+ Providing patients with a description of pharmacy messaging programs;
+ Providing an opportunity to opt out of the pharmacy messaging programs;
+ Ensuring that opt-out mechanisms function properly;
+ Identifying sponsorship;
+ Disclosing limitations of materials as a source of health care information;
+ Providing information that is clear and reliable;
+ Endeavoring to use discretion in communicating about sensitive subjects;
+ Ensuring that persistence and adherence messages are written in a manner consistent with available data about the characteristics of effective messaging; and
+ Engaging in messaging about alternative and/or adjunctive therapies only when there is a clear potential benefit to patients.

Even with these voluntary principles, however, HIPAA does not preempt state law, which is why a number of states have enacted, or are considering, legislation to restrict the ability of pharmacies to conduct adherence messaging programs. As with the federal anti-kickback statute, the unintended consequence of some of these state laws is uncertainty about which types of medical information require patient authorization and which do not. For example,

[1] 42 C.F.R. Part 1001.

[2] To the extent that the antikickback statute discourages refill reminders and other compliance programs, its effect is somewhat at odds with the Medicare Modernization Act, which required that, every Part D benefit plan implement medication management therapy programs (MTMPs). MTMPs are designed to optimize the therapeutic outcome of drug treatment for certain beneficiaries through education and management programs. Improved medication compliance and adherence is a key part of a successful MTMP.

[3] Pub. L. No. 104-191.

[4] 45 C.F.R. § 164.506(a) and (c).

the California Confidentiality of Medical Information Act (CMIA) provides (in relevant part):

> Except to the extent expressly authorized by the patient . . . no provider of health care . . . shall intentionally share, sell, use for marketing, or otherwise use any medical information *for any purpose not necessary to provide health care services* to the patient.[5]

When read literally, the CMIA seems to prohibit adherence-messaging programs without specific authorization, when in fact, the Act views these programs as "necessary to provide health care services" and exempts this requirement. The CMIA also exempts the authorization requirement for adherence communications that address a "chronic and seriously debilitating or life-threatening condition" if certain conditions are satisfied.[6] But since there is uncertainty as to how state regulators could interpret these provisions, many pharmacies and pharmaceutical manufacturers have opted not to run adherence programs in California, or run them on a limited basis. The consequence is that adherence communications for medications for diabetes, osteoporosis, asthma, hypertension and heart attack and stroke prevention now being provided in other states are, in some cases, being withheld from Californians. The same situation could result if a number of state bodies enact legislation that broadly prohibit the use of prescription drug information for commercial purposes, including pharmacy-based programs funded through third parties.

LIMITED FEDERAL SUPPORT FOR ADHERENCE RESEARCH

Besides federal and state laws and policies that impact the availability of adherence assistance programs, insufficient federal funding for adherence research is another impediment to improving medication use. Although created the Adherence Research Network to identify research opportunities at its 18 Institutes and Centers, the Network has been inactive since 2002. Moreover, in 2000, when the Network was funding adherence research, the actual NIH dollars earmarked for testing interventions to improve medication-taking behavior was only $3 million in a budget of nearly $18 billion.[59] The overall NIH budget in 2000 was $17.8 billion.

Such paucity in adherence research funding has implications for public policy, as policymakers look to researchers to help determine priorities for the medical community. While NIH dollars are being spent on patient adherence as it applies to treating specific disease states, very little is actually going into testing interventions and measuring their effectiveness. Thus, a key goal will be to re-invigorate the Adherence Research Network while increasing substantially the level of NIH funding for research to test adherence interventions and measure their effectiveness.

Kripalani, Yao, and Haynes (Interventions to Enhance Medication Adherence in Chronic Medical Conditions) point out key limitations and challenges for future adherence research, noting that because most of the available literature does not separate out the effects of the individual components of multifaceted interventions, it is not possible to draw definitive conclusions about which features of combined interventions are most beneficial.[60] Additional research, the authors note, is needed to clarify which features are most responsible for changes in adherence and clinical outcomes, with the caveat that individual components may not prove powerful enough to show important effects.

Future studies should also examine the effect of varying the intensity of interventions to determine dose response relationships. Such findings would have important implications for health systems considering the implementation of patient adherence programs on a large scale. Investigations should be conducted with clinically meaningful outcomes as the primary end points and be sufficiently powered to detect a difference in these measures. Most important, future research should seek to understand the determinants of adherence behavior and to develop and test innovative ways to help people adhere to prescribed medication regimens, rather than persisting with existing approaches.[60]

[1] Cal. Civ. Code § 56.10(d), as amended by A.B. 715.

[2] Cal. Civ. Code § 56.05(f)(3).

Strategies for Improving Patient Adherence

How do we change behavior? How can we motivate patients with chronic illnesses to take steps that will keep their diseases from progressing? How can we engage health professionals to intervene with patients and their caregivers about the need to take medicines as directed -- sometimes for life? And how can we elevate the subject of prescription medicine adherence, an issue to which Americans have been largely indifferent, to one that is both compelling and actionable by all affected stakeholders?

These are the challenges facing the U.S. health system at a time when lack of patient adherence to medication regimens, especially for the treatment of chronic conditions, leads to unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and even death. To address this serious problem, a range of strategies must be used to target the underlying causes of poor adherence and to make the relevance of taking medicines as prescribed meaningful to all stakeholders -- patients, caregivers, clinicians, payors, public health advocates, and policymakers. But this does not mean starting from scratch: extensive research exists that provides insights into effective approaches to improve adherence to therapeutic regimens.

RECOGNIZING THE DISEASE CHARACTERISTICS OF NONCOMPLIANCE

The 1994 report *Noncompliance With Medications: An Economic Tragedy With Important Implications for Health Care Reform* introduced the concept that non-adherence is a disease because the problem shares many features of a medical disorder, including:[22]

+ Non-adherence can lead to increased morbidity and mortality;
+ The problem can be assessed and monitored;
+ Effective interventions have been identified;
+ Triage is needed to identify those patients at greatest risk of non-adherence; and
+ Non-adherence is a public health problem for which prevention is an important goal.

In light of these similarities, approaching non-adherence as a disease could be an important step towards increasing the extent to which patients take their medications as prescribed by their health care provider(s). With implications for research, health policy, and the day-to-day practice of medicine and pharmacy, widespread recognition of the disease characteristics of non-compliance would put the issue into a new perspective that would help gain the attention, focus and sustained commitment that this problem deserves.

INCREASING PUBLIC AWARENESS THROUGH EDUCATION

To motivate patients to adhere to their medication regimens, the American public must first recognize the role each person plays in taking their medications as prescribed or in making sure that a loved one does so. Simply put, the American public needs increased education about medication adherence that captures their attention, increases their understanding, and enhances their motivation to take their prescribed medication in the recommended way.

To achieve these goals, specialists in medication use advocate mounting a sustained, national public education campaign to provide patients and caregivers with meaningful information about adherence that they can incorporate into their daily lives. Ultimately, enlisting the support and participation of many stakeholders -- including the public health community, physicians and other

prescribers, nurses, pharmacists, the pharmaceutical industry, government, private payors, and consumer organizations – such a campaign must elevate adherence as a health priority and utilize multiple information channels to engage the public on a sustained basis. Only by making the public aware of the role individuals play in the management of their own health conditions will we empower people to ask questions about their medicines, fill their prescriptions, and follow their treatment regimens as recommended.

PATIENT INFORMATION STRATEGIES

As noted by the American Heart Association, the rationale for enhancing adherence is based on the premise that the patient will get well or stay well if the physician, other health care providers, and the health care organization make appropriate recommendations, providing the patient has the requisite knowledge, motivation, skills, and resources to follow the recommendations. Specifically, the American Society of Consultant Pharmacists states that patients need to know:[61]

- What condition the medicine was prescribed to treat.
- What the medicine is, why it is needed and how it works in the body.
- Why the medicine was selected.
- The dosage schedule and related instructions about how to take the medicine (before eating, with food, etc).
- Whether the medicine will work safely with other medicines being taken (both prescription and nonprescription medicines).
- What to do if doses are missed or delayed.
- The common adverse effects that may occur and what to do about them.
- How to monitor whether the medicine is having its intended effect (are lab tests or blood work necessary; if so, how often).
- Serious adverse effects to look out for and what to do if they occur.
- What action to take when the prescription is about to run out.

In the outpatient setting, the primary opportunities for providing this information to the patient occur in discussions when the prescriber writes the prescription and when the patient fills the prescription at the pharmacy. Visiting nurses in the home setting also have an opportunity for such dialogue with patients. During these discussions, research has found that relaying the most important information first, repeating key points, and having patients restate key instructions increase patient understanding.[62] Moreover, data show that providing patients with information about possible adverse effects does not appear to decrease adherence.[63]

Besides providing basic information about how to take the medication correctly, an important reason for clinicians to educate patients about their medication regimens is to address common misperceptions that lead to non-adherence. This may include the perception that the medication can be stopped when the condition improves or that the medicine is only needed when there are symptoms. Moreover, studies demonstrate the benefits of improved adherence when patients are encouraged to ask questions and share information. This process is built upon the Health Belief Model, one of the most widely used conceptual frameworks in health behavior, which suggests that people's beliefs guide their understanding of and response to their diseases.[26]

However, since studies find patients forget more than half of the information from a verbal explanation immediately after they hear it,[17] health care providers should welcome patients who bring a partner or caregiver as a "second set of ears," and should ask patients to repeat instructions and encourage note taking during the oral discussion. Complementing these actions, providing written information about the medication has been shown to improve patients' knowledge and decrease medication errors. A 2007 study conducted by researchers at the Arnold &Marie Schwartz

College of Pharmacy and Health Sciences, Long Island University, found that approximately two-thirds of surveyed patients reported reading the non-manufacturer developed consumer medicine information (CMI) leaflets about new medications provided by pharmacies.[64] Accordingly, the study recommends that pharmacists should encourage patients to read the CMI leaflet and promote it as a useful resource, although this information should be used in conjunction with, but not as a substitute for, oral discussions.[40]

In the case of teaching complex medication-taking techniques, such as using a metered dose inhaler or administering an injection, oral and written information will not suffice. Here, patients need a health care provider to walk them through the process in easy steps and to observe while the patient repeats the procedures. The health care provider is then able to answer questions, point out any problems with the patient's technique and work with the patient to repeat the procedure until the problems are resolved.

While all these strategies are helpful in promoting patient adherence, how the information is conveyed also matters greatly to how patients ultimately respond. For example, a 2006 study conducted for the American College of Physicians (ACP) Foundation and reported in the *Annals of Internal Medicine*[65] found that a major barrier to patient adherence is patient understanding of prescription drug labels, including the format, content, and use of medical jargon. Because this problem is especially acute among those with lower literacy (eighth grade level or below) and patients taking multiple prescription drugs, the ACP Foundation has launched a Prescription Medication Labeling project to address the problems associated with poor health communication.

A key strategy of the Prescription Medication Labeling project is the use of patient-centered counseling, an approach that focuses not only on the content of the information but also on the tone used by health professionals. As detailed in the 1995 NCPIE report, patient adherence improves when professionals:[36]

+ Are warm and caring and respect the patient's concerns,
+ Talk to patients directly about the need for adherence,
+ Probe patients about their medicine taking habits and health beliefs,
+ Obtain agreement from the patient on the specifics of the regimen, including the medical treatment goals,
+ Communicate the benefits and risks of treatment in an understandable way that fosters the perception that the patient has made an informed choice about his or her care, and
+ Probe for and help resolve patient concerns upfront so they do not become hidden reasons for non-adherence.

BEHAVIORAL REINFORCEMENT AND PATIENT SUPPORT

Especially in chronic disease management, where medication is required on a continuing basis, adherence with medication regimens involves a change in behavior on the part of the patient.[66] In some cases, patients may need to take specific medications every day at a set time. Adherence also requires that patients remember to get their prescriptions refilled and to incorporate their medication taking into their daily schedules and lifestyle.

Because these actions require diligence, adherence can be viewed as a continuum, with most patients starting as very diligent and declining over time. Adherence has also been shown to decline between visits to the physician/clinic.[3] That is why regular interaction between patients and health providers is so important for improving medication use.

Recognizing these challenges, adherence researchers stress the importance of tailoring the medication regimen to the patient's daily schedule and lifestyle, such as:

- Decreasing the number of daily doses to once or twice a day;[17, 36]
- Eliminating unnecessary or redundant medications or using combination products when possible;
- Changing the route of administration, such as using oral medications or transdermal patches; and
- Decreasing the overall cost of the medication regimen if affordability is a barrier to compliance.

Additionally, long-term adherence requires behavioral reinforcement and patient support strategies throughout the continuum of care. Providing cues to patients -- through medication packaging that helps patients chart and remember to take each dose and through tools such as medication organizers and reminder charts -- have been shown to improve adherence. A personal medication chart encourages the patient to keep a list of all the prescription and over-the-counter medications used, including recording how much to take, when and how to use the medicine, why to use the medicine, and the name of the prescriber.

Another approach that has produced measurable outcomes is direct-to-patient adherence programs, such as arranging supportive home visits by health care providers or encouraging the patient to establish a buddy system with a friend who also takes daily medication. In a meta-analysis of 153 studies assessing the effectiveness of different adherence interventions, those that combined educational and behavioral approaches were more successful than single-focused interventions.[67]

Along with these strategies, specialists in the field are advocating for broader awareness and adoption of new technologies that make it possible to engage patients more effectively about medication adherence. For example, prescribers can use email to communicate directly with patients who are encouraged to ask questions electronically. Pharmacies can use adherence-messaging programs to reach patients using letters, newsletters, brochures, telephone calls, e-mails, faxes and even pagers. These programs can be triggered by automated pharmacy dispensing records, based on estimates of when the patient may run out of the medication. These communications not only remind the patient to refill the prescription but also emphasize the importance of following their health care provider's instructions and keeping follow-up visits.

Other technological innovations that have the potential to improve medication adherence include electronic reminder devices and automated medication dispensers. For example, electronic pillboxes are available that can be programmed to light up when a dose is due. Also in development is new technology that allows a microchip to be embedded in the packaging to monitor the dates and times when the package is opened, allowing pharmacies to scan the information and plot out patients' medication taking patterns.

STRATEGIES DIRECTED AT HEALTH PROFESSIONALS

Although ultimately patients must make the decision to fill their prescriptions and take their medicines as prescribed, improved adherence requires the successful interplay between the patient and those involved in managing his/her care -- the physician, physician assistant, nurse or nurse practitioner, and pharmacist. This partnership is the principle behind patient-centered medicine,[68] where clinicians cooperate directly with the patient in designing, implementing and monitoring a therapeutic plan.

Shifting to a patient-centered approach, however, requires that health care providers have the knowledge to educate and counsel about medication adherence. As a result, specialists advocate starting with increased training of prescribers, nurses and pharmacists to improve their adherence-related skills.[68] Currently, courses in patient education and adherence promotion are incorporated into the curriculum of many nursing and pharmacy schools, but there are major gaps, especially in the training of medical students. It is not surprising then that even among health care

professionals, studies find that lack of medication adherence is a problem.[16]

To fill this troubling education gap will require developing a curriculum that will allow medical, nursing and pharmacy students to conceptualize and execute responsible medication-related problem-solving on behalf of individual patients. Curricula should be designed to produce graduates with sufficient knowledge and skills to provide patients with adherence education and counseling competency. Expanding the core competencies of clinicians also requires a significant investment in expanding professional education through courses provided by recognized medical sub-specialty and allied health organizations as well as lecture series on patient adherence.

At the same time, improving the ability of patients to adhere to their therapy regimens necessitates an expanded role for pharmacists, who are among the most accessible members of the health care team once medication therapy is initiated.[3] There is also growing evidence that pharmacy-based interventions are effective in improving drug therapy results. For example, in a study where pharmacists provided adherence counseling to patients with high blood cholesterol, medication adherence improved from a national average of 40 percent to 90 percent.[69]

To capitalize on the role of pharmacists as the nexus for conducting adherence interventions, the pharmacy community has been working to implement collaborative drug therapy management (CDTM) through which pharmacists and physicians voluntarily enter into agreements to jointly manage a patient's drug therapy.[70] Currently, 40 states have specific laws that allow CDTM and others are developing or reviewing proposed legislation to enable CDTM for improved disease and drug therapy management.[56]

At the same time, more initiatives like the "Asheville Project," the longest-running test using pharmacist interventions to improve patient adherence with diabetes and asthma regimens, are needed to improve health outcomes.[71] Featuring patient counseling, the Asheville Project provides pharmacists with intensive training in managing the target disease and then pays them for monthly consultations with patients, during which they encourage those patients to adhere to the recommended lifestyle changes and prescribed medication regimen. Currently, the American Pharmacists Association (APhA) Foundation has launched the Diabetes Ten City Challenge modeled after the Asheville Project to improve medication adherence among people with diabetes.[72] This demonstrates that matching patients with specially trained pharmacists is a useful strategy to help patients learn how to manage their disease more effectively while lowering the costs of health care.

Pharmacists should also take advantage of advances within the practice that make patient adherence efforts more effective. This includes designating areas within the pharmacy that are conducive to patient counseling and undertaking such activities as monitoring blood pressure, blood glucose levels and other patient screening activities. Further, adherence technologies now make it possible for pharmacists to conduct direct-to-patient counseling programs tailored to the needs of patients who have been prescribed medication in virtually every therapeutic class. These programs can be implemented in various forms, including education and reminder letters, e-mail messages, newsletters, brochures, and phone calls.

THE NEED FOR A MULTIDISCIPLINARY APPROACH TO IMPROVE ADHERENCE

If the goal of medication adherence is to improve the outcome for each patient through the correct use of prescribed medicines, then what is ultimately needed is a multidisciplinary approach to adherence management whereby the patient and all members of the health care team work together to cure the patient's illness, provide symptom relief, or arrest the disease process. This approach is intended to convey a respect for the goals of both the patient and the health professional, and envisions patients and clinicians engaging in a productive discussion about medication regimens.

The idea of a multidisciplinary team is the concept behind the term "concordance" advanced by the Royal Pharmaceutical Society of Great Britain[11] and other European bodies, and behind the term "pharmaceutical care,"[57] which has gained traction within the U.S. Regardless of the term, the underlying premise is what NCPIE calls the "Medication Education Team," a model of open communication and shared responsibilities in which physicians and other prescribers, nurses, pharmacists and other providers communicate with patients at every "teachable medicine moment," making communication a two-way street, listening to the patients as well as talking to them about their medicine use. Since the 1980s, NCPIE has advocated for the formation of a "Medicine Education Team" for every patient, so each individual is fully informed about each medicine he/she is taking, has the instructions for taking these medicines properly, and knows the medication risks to avoid.

Recognizing that many interventions have been shown to be effective in improving adherence rates, the World Health Organization (WHO) report specifically calls on health professionals, researchers, health planners and policymakers to implement a multidisciplinary approach to adherence education and management.[3] This has led to the creation of a special Task Force on Medicines Partnership in the United Kingdom.[73] In the United States, pharmacy researchers are also examining ways to demonstrate the benefits of pharmacy-based adherence intervention services. What is needed now is for leading physician, nursing, and pharmacy organizations to embrace NCPIE's concept of the Medicine Education Team, resulting in its widespread adoption in clinical settings.

THE NEED FOR SUPPORTIVE GOVERNMENT POLICIES

At a time when the number of prescriptions dispensed in the U.S. is expected to grow to 4.5 billion by 2010,[74] enabling pharmacists to use the most modern technologies to conduct adherence assistance programs would seem obvious. However, as noted previously, there are a variety of impediments, including limitations by a number of federal and state laws. An immediate need is to resolve ambiguities about whether sponsored programs fall within the scope of the federal anti-kickback statute, and to ensure that federal and state medical privacy laws make clear that pharmacies may communicate with patients about the importance of adherence to prescribed courses of therapy, as long as such compliance programs address privacy-related concerns.

THE NEED FOR RESEARCH SUPPORT AND RESEARCH RIGOR

With the astonishing advances in medical therapeutics during the past two decades, one would think that studies about the nature of non-adherence and the effectiveness of strategies to help patients overcome it would flourish. On the contrary, the literature concerning interventions to improve adherence with medications remains far from robust. Compared with the many thousands of trials for individual drugs and treatments, only a few relatively rigorous trials of adherence interventions exist and these studies provide limited information about how medication adherence can be improved consistently using the resources usually available in the clinical settings.[75]

At the same time, there has been inadequate funding from the NIH for research on the causes of non-adherence and the interventions needed to improve adherence across types of health-care professions, settings, interventions, and persons of varying educational, economic, and ethnic backgrounds. Policymakers must re-examine how research on patient adherence is addressed within NIH with the goal of significantly increasing funding for research on interventions to improve adherence. While the creation of the Adherence Research Network is a good start, now is the time to invest in adherence research to identify behaviorally sound multi-focal interventions across diseases and in different service delivery environments.

Advancing Adherence:
A National Action Agenda

10 PRIORITIES FOR ACTION

Mounting evidence shows that poor medication adherence is pervasive and costly. The problem affects all ages, both genders and people of all socioeconomic levels. Non-adherence is particularly important for patients with chronic conditions as it leads to unnecessary disease complications, reduced functional abilities, a lower quality of life and too often, premature death.

Because of the nature and extent of this challenge, NCPIE has described non-adherence as America's "*other drug problem*." NCPIE, along with NIH, WHO, and numerous voluntary health and professional societies around the world, has contributed a new understanding about the importance of adherence for successful treatment. The consensus of all stakeholders is that interventions that improve patient adherence enhance health status and reduce health care costs.

But this consensus is only the beginning of what is needed to address the problem of patient nonadherence. Adherence problems have been generally overlooked as a serious public health issue and, as a result, have received little direct, systematic, or sustained intervention. Moreover, Americans have inadequate knowledge about the significance of medication adherence as a critical element of their improved health. Thus, a major, sustained public education effort is required to educate people before they become ill, to prepare them to respond positively to adherence information when faced with a condition requiring medication.

Because the stakes are so high, NCPIE has become a convener and catalyst for promoting a dialogue on new ways to advance patient medication adherence across the continuum of care -- from diagnosis through treatment and follow-up patient care and monitoring. Accordingly, NCPIE convened a panel of experts to create consensus on ten national priorities that may have the greatest impact on improving the state of patient adherence in the U.S. Ultimately involving the support and active participation of many stakeholders -- the federal government, state and local government agencies, professional societies and health care practitioners, health educators, and patient advocates -- this platform calls for action in the following areas:

1. **Elevate patient adherence as a critical health care issue.**
   Medication non-adherence is a problem that applies to all chronic disease states; affects all demographic and socio-economic strata; diminishes the ability to treat diabetes, heart disease, cancer, asthma, and many other diseases; and results in suffering, death, and sub-optimal utilization of health care resources. Despite this impact, patient adherence is not on the radar screen of policy makers and many health professionals, which has meant inconsistent government policies and a lack of resources for research, education, and professional development. Until health care policy makers, practitioners and other stakeholders recognize the extent of non-adherence, its cost, and its contribution to negative health outcomes, this problem will not be solved.

2. **Agree on a common adherence terminology that will unite all stakeholders.**
   Today, a number of common terms -- compliance, adherence, persistence, and concordance -- are used to define the act of seeking medical attention, filling prescriptions and taking medicines appropriately. Because these terms reflect different views about the relationship between the patient and the health care provider, confusion about the language

used to describe a patient's medication-taking behavior impedes an informed discussion about compliance issues. Therefore, the public health community should endeavor to reach agreement on standard terminology that will unite stakeholders around the common goal of improving the self-administration of treatments to promote better health outcomes.

3. **Create a public/private partnership to mount a unified national education campaign to make patient adherence a national health priority.**
To motivate patients and practitioners to take steps to improve medication adherence, there must be compelling and actionable messages as part of a unified and sustained public education campaign. A foremost priority is creating the means by which government agencies, professional societies, non-profit consumer groups, voluntary health organizations and industry sectors can work together to reach public and professional audiences on a sustained basis. Although NCPIE and a number of government agencies, professional societies and voluntary health organizations are promoting information about medication adherence, there also needs to be a national clearinghouse, serving as the catalyst and convener so that all stakeholders can speak with one voice about the need for improving patient adherence. NCPIE, a professional society, or an academic institution could manage this clearinghouse effectively.

4. **Establish a multidisciplinary approach to compliance education and management.**
There is a growing recognition that a multidisciplinary approach to medication taking behavior is necessary for patient adherence to be sustained. This has led NCPIE to promote -- the "Medication Education Team" -- in which the patient and all members of the patient's health care team work together to treat the patient's condition, while recognizing the patient's key role at the center of the process. Looking to the future, this model has the potential to improve adherence rates significantly by changing the interaction between patients and clinicians and by engaging all parties throughout the continuum of care.

5. **Immediately implement professional training and increase the funding for professional education on patient medication adherence.**
Today's practitioners need hands-on information about adherence management to use in real-world settings. This need comes at a time when a solid base of research already exists about the steps physicians and other prescribers, pharmacists, and other health care practitioners can take to help patients improve their medication taking behavior. Professional societies and recognized medical sub-specialty organizations should immediately apply these research findings into professional education through continuing education courses as well as lecture series on patient adherence issues.

6. **Address the barriers to patient adherence for patients with low health literacy.**
Low health literacy and limited English proficiency are major barriers to adherence and deserve special consideration. Thus, an important target for patient-tailored interventions are the 90 million Americans who have difficulty reading, understanding and acting upon health information. Accordingly, advocates recommend widespread adoption of existing tools, such as the Rapid Estimate of Adult Literacy in Medicine Revised (REALM-R), validated pictograms designed to convey medication instructions, and specific patient education programs that promote and validate effective oral communication between health care providers and patients supported by the provision of adjunctive useful information in its most useful

format to address the patient's individual capabilities.

7. **Create the means to share information about best practices in adherence education and management.**
Today, stakeholders have access to more than 30 years of research measuring the outcomes and value of adherence interventions. Building on this foundation, a critical next step is for the federal government -- through the Adherence Research Network -- to begin collecting data on best practices in the assessment of patient readiness, medication management and adherence interventions, incentives that produce quality outcomes from adherence interventions, and measurement tools so that this information can be quantified and shared across specialties and health care facilities. Just as federal and state registries collect and share necessary data on different disease states, a shared knowledge base regarding systems change, new technologies, and model programs for evaluating and educating patients about adherence will significantly improve the standard of compliance education and management.

8. **Develop a curriculum on medication adherence for use in medical schools and allied health care institutions.**
Lack of awareness among clinicians about basic adherence management principles remains a major reason that adherence has not advanced in this country. To change this situation will require institutionalizing a curriculum at medical, nursing, pharmacy and dental schools as well as courses for faculty members that focus on the adherence advancement and execution of medication-related problem solving. Moreover, once these courses are developed, it will be important for academic centers to elevate patient adherence as a core competency by mandating that course work in this area be a requirement for graduation.

9. **Seek regulatory changes to remove road-blocks for adherence assistance programs.**
Improved adherence to medication regimens is predicated on supportive government policies. Unfortunately, a number of federal and state laws and policies now limit the availability of adherence assistance programs. Accordingly, language in these federal and state laws that limits communications to patients about medication adherence must be identified for lawmakers and regulators to resolve. Key issues to be addressed include clarifying that education and refill reminder communications fall within the scope of the federal anti-kickback statute, and ensuring that federal and state laws related to patient privacy and the use of prescription data do not unduly limit the ability of pharmacies to communicate with patients about the importance of adhering to their prescribed courses of therapy.

10. **Increase the federal budget and stimulate rigorous research on medication adherence.**
Although the National Institutes of Health has put in place the Adherence Research Network to identify research opportunities at its 18 Institutes and Centers, the actual NIH dollars earmarked for testing interventions to improve medication taking behavior was only $3 million in a budget of nearly $18 billion in 2000, the latest date available. Thus, it will be important for stakeholders to advocate for NIH to significantly increase the proportion of its research funding to test adherence interventions and measure their effectiveness. Even if NIH triples its 2000 commitment, the small amount spent on patient adherence will still signal that the issue is a critical area for new research efforts.

THE TIME IS NOW

Creating a public policy agenda that elevates patient non-adherence as a priority concern is essential to reduce the adverse health outcomes and economic consequences associated with this pervasive problem. Improving how and when patients take their medicines is a complex challenge, requiring changes in the knowledge, attitudes, and skills of patients, health professionals, and policy-makers alike. While no single strategy will guarantee that patients fill their prescriptions and take their medicines as prescribed, it is hoped that the priorities identified in this report will serve as a catalyst for action and offer realistic goals for improving the standard of medication adherence through research, education, and policy changes.

Now is the time to improve patient care, recognizing the importance of medication adherence, and providing the resources and attention that are required.

Table 1

MAJOR PREDICTORS OF POOR ADHERENCE TO MEDICATION ACCORDING TO STUDIES OF PREDICTORS

Predictor:	**Presence of psychological problems, particularly depression**
Study:	vanServelien et al., Ammassari et al., Stilley et al.
Predictor:	**Presence of cognitive impairment**
Study:	Stilley et al., Kino et al.
Predictor:	**Treatment of asymptomatic disease**
Study:	Sewitch et al.
Predictor:	**Inadequate follow-up or discharge planning.**
Study:	Sewitch et al., Lacro et al.
Predictor:	**Side effects of medication**
Study:	van Servellen et al.
Predictor:	**Patient's lack of belief in benefit of treatment**
Study:	Okuno et al., Lacro et al.
Predictor:	**Patient's lack of insight into the illness**
Study:	Lacro et al., Perkins
Predictor:	**Poor provider-patient relationship**
Study:	Okuno et al., Lacro et al.
Predictor:	**Presence of barriers to care or medications**
Study:	van Servellen et al., Perkins
Predictor:	**Missed appointments**
Study:	Servellen et al., Farley et al.
Predictor:	**Complexity of treatment**
Study:	Ammassari et al
Predictor:	**Cost of medication, copayment, or both**
Study:	Balkrishnan, Ellis et al.

(Source: N Engl J Med 353:5 www.nejm.org August 4, 2005, page 491)

Table 2

STRATEGIES FOR IMPROVING ADHERENCE TO A MEDICATION REGIMEN*

+ Identify poor adherence
  - Look for markers of nonadherence: missed appoint¬ments ("no-shows")
  - Lack of response to medi¬cation, missed refills
  - Ask about barriers to adherence without being con¬frontational
+ Emphasize the value of the regimen and the effect of adherence
+ Elicit patient's feelings about his or her ability to follow the regimen, and if necessary, design supports to promote adherence
+ Provide simple, clear instructions and simplify the reg¬imen as much as possible
+ Encourage the use of a medication-taking system
+ Listen to the patient, and customize the regimen in accordance with the patient's wishes
+ Obtain the help from family members, friends, and community services when needed
+ Reinforce desirable behavior and results when appropriate
+ Consider more "forgiving"** medications when adherence appears unlikely
  - Medications with long half-lives
  - Depot (extended-release) medications
  - Transdermal medications

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* Information in this table was adapted from Osterberg and Rudd (Osterberg, LG, Rudd, P. Medication Adherence for Antihypertensive Therapy. In: Oparil S, Weber MA, eds. Hypertension: a comparison to Brenner and Rector's The Kidney. 2nd ed. Philadelphia: Elsevier Mosby, 2005:848

** Forgiving medications are drugs whose efficacy will not be affected by delayed or missed doses.

(Source: N Engl J Med 353:5 www.nejm.org August 4, 2005, page 493)

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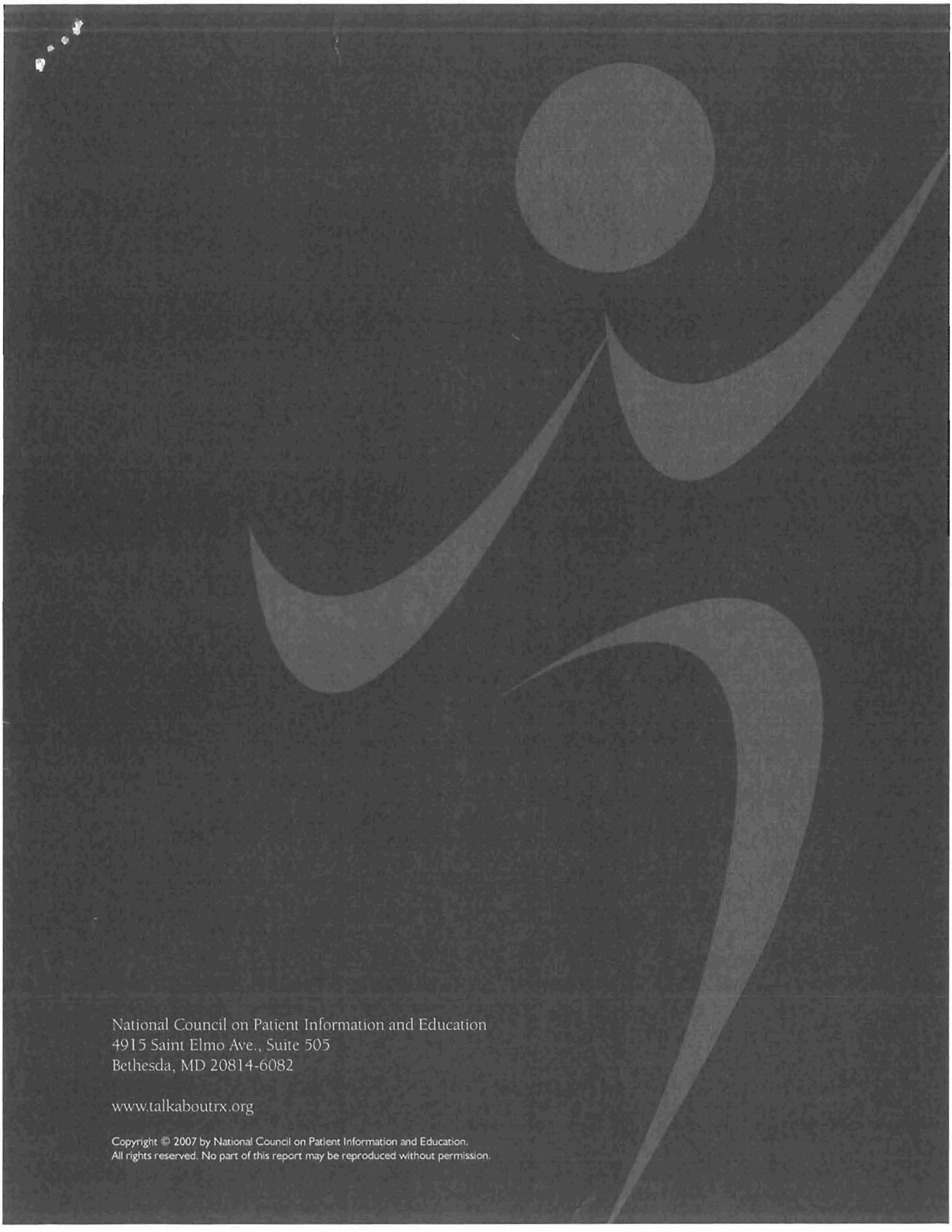

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'Take as directed' a lot easier with these new tools

'Take as directed' a lot easier with these new tools

Aug 20, 2007
By: Joe Dysart
Drug Topics Supplements

Given that patient compliance with drug regimens is a perennial problem, it's no surprise that vendors continue to roll out new technologies designed to beep, text message, or color-code patients along their way to better health.

According to a report released this month from the National Council on Patient Information and Education (NCPIE), patients not experiencing acute symptoms are less likely to adhere to their medications. The report added that only 51% of patients with high blood pressure stick with their medications.

"Compliance problems are rampant for reasons that are multitudinous and varied," said Katherine Binns, senior VP of healthcare research at Harris Interactive, a market research firm. "These barriers leading to noncompliance present significant challenges."

Manufacturers are unleashing a slew of products featuring state-of-the-art technology intended to help increase compliance. Many of these items employ computerized components that can monitor patient compliance from afar using Web-based software or wireless text-messaging systems. Other solutions include local alarm systems, which beep to remind a patient when it is time to take a medication, or the means to talk to patients in computer-generated voices about their medications and the dosage regimen they are supposed to follow.

Here's a look at some of the latest compliance newbies featuring such cutting-edge technology.

Getting personal

- Parata's **PACMED** is a strip packaging solution that generates user-friendly, personalized unit-of-dose medication pouches for use in stores and at long-term care facilities.


PACMED system and unit-of-dose pouches

"Servicing the prescription needs of long-term care facilities offers a lucrative business opportunity to pharmacies, but the high labor commitment of traditional compliance packaging often creates a barrier," said Nanette Kirsch, a Parata spokeswoman. "Parata's PACMED is an essential tool that solves that problem, offering significant advantages over blister packaging."

The packaging, which is covered under Medicare MTM as compliance packaging, processes up to 60 unit-dose packages or 50 multi-dose packages per minute and seamlessly aligns inventory with patient demand. Plus, the included Server+ software facilitates multi-tasking and maximum pharmacy productivity, according to Kirsch.

"Custom-printed unit-of-dose pouches ensure that the right patient gets the right medications at the right time, every time," Kirsch said. "Plus, the system reduces inventory costs, since, as class A packages, most unused medications can be returned to stock."

Other perks of the system include the ability to include personalized directions, such as "8 AM" or "breakfast"; the ability to help patients identify when a dose has been missed; or convenient portability of doses.

Electronic compliance

• MeadWestvaco's **Cerepak**, billed as "electronic compliance packaging," is yet another new product. Cerepak is designed to accurately record the date and time each dose of medication is taken. In addition, sensors in the packaging monitor the specific tablet or tablets being removed by a patient.

The system also enables patient dosing data, as well as any other data collected, to be fed to a personal computer or uploaded to Web-based compliance-analysis software that is maintained by a pharmacy, doctor, or other healthcare professional.

Packaging for Cerepak is available in many formats, including MeadWestvaco's Dosepak packaging, which features an outer carton for ample billboard space, a fold-over blister card, and an attached insert for patient education and prescription directions. Dosepak can also include a micro CD, as well as patient quality-of-life questionnaires, which can request feedback regarding side effects of drugs taken.

• **DailyMed**, from PrairieStone Pharmacy, is a pharmacy dispensing system available only at PrairieStone Pharmacies. DailyMed sorts and organizes monthly prescriptions, over-the-counter medications, and even vitamins, into convenient, single-dose packets.

The technology does not accommodate all medications, but it does accommodate half-tablets.

Beep, beep

• Still another new compliance entry is INRange Systems' **Electronic Medication**

Management Assistant. EMMA is a remote prescription management system placed in a patient's home, enabling a healthcare professional to manage and dispense medication. About the size of a breadbox, the unit is outfitted with two-way communications software that links a patient and a healthcare professional via the Web. When a prescribed medication is scheduled to be taken, the unit emits a beep. The patient then releases the medication by activating a dispensing mechanism, and the unit records the event for follow-up monitoring by a healthcare professional. EMMA also enables a doctor or pharmacist to remotely schedule or adjust a patient's prescribed medications via the Web.

DailyMed

Rex the Talking Bottle

• MedivoxRx's **Rex the Talking Bottle** is yet another unique product. Activated by pressing and holding a button at the base of the bottle, this product offers a recorded voice description of the bottle contents, as well as dosage instructions. Pharmacists can make sound recordings for prescriptions using text-to-speech technology. Essentially, when a pharmacist sends label data to the printer, the label information is transformed into a computer-generated recording on the bottom of the bottle.

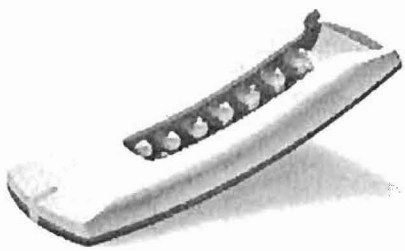
Pill nanny

• And if that's not enough, SIMpill has launched **SIMpill Medication Dispenser**, a "pill nanny" that monitors patient adherence to a dosage regimen via text messaging, and can take added steps should a patient miss a dosage.

SIMpill Medication Dispenser

The crux of the system is a text messaging-enabled pill bottle, which sends a text message to the computer of a health professional each time a patient opens the bottle and takes his or her medication at the prescribed time. Should a prescribed dosage event be missed, the system's software can be programmed to generate a number of responses, including sending a text message to the cell phone of a family member that the patient has not taken medication at a prescribed time.

The system can also send a similar text message to a clinic-based healthcare professional, and continue to send text messages wherever needed on an escalated basis if noncompliance continues.



The Helping Hand

• Another unique compliance tool is **The Helping Hand**, from Medicom. This handheld device, with a blister-card inside, reminds a patient when it's time to take medication using acoustic or visual clues. The device's software also monitors overall compliance with a medication regimen, offering patients feedback via a visual signal—red, yellow or green—as to how well they are complying with a regimen.

Text messaging

• There's also Med-Prompt's **Med-Prompt** text-messaging system, which reminds patients to take medication at a predetermined time via text messages that the company sends to most common communication devices, including cell phones, PalmPilots, and BlackBerrys.

Patients provide their medication regimen to Med-Prompt via phone. They can make alterations to that regimen at any time via a toll-free number at no extra charge.

• InforMedix Holdings is offering the **Med-eMonitor System** interactive "smart pillbox," a monitored medication adherence solution. Infor-Medix has partnered with Rodman's Discount Drug Stores, located in the Washington, D.C., area as part of its consumer launch of the Med-eMonitor System. Under the agreement, Rodman's will initially offer the product to consumers through its flagship store in Washington, D.C. It has the option to expand the program to its other sites.

The Med-eMonitor System

The product is designed to enhance the medication and care plan adherence of selected customers, including those who require chronic care and are taking multiple medications, or who have difficulty taking their medications on a timely and consistent basis.

The Med-eMonitor System consists of a portable patient-interactive "smart pillbox" about the size of a videotape, and has multiple medication storage compartments, an LCD screen, a keypad, and a telephone jack. At scheduled intervals, patients are instructed by the device to take their prescribed medicine, and then asked to confirm whether they have taken their medications. The drawers hold about a month's supply of medicine. It also records the date and time a medicine drawer is opened and prompts patients to answer questions and complete other related tasks.

According to Bruce Kehr, M.D., CEO/ chairman of InforMedix, a large-scale rollout of the system to consumers nationwide is planned.

• Finally, OnTimeRx is offering **On TimeRx Software**. This software package can be loaded onto any computerized device to remind patients to take their medication.

Patients simply keypunch in data about their medication regimen, and their computerized units spit out alerts at the appropriate times for taking medication. Each drug alarm screen also displays the remaining day's supply for each medication, and a "take now" button is made available to enable a patient to record the taking of a dose.

Public Ed

mnegrete@PharmacyFoundation.org

....Discover the People & Power of Pharmacy

Aug 01, 2007 08:00 ET

America's Other Drug Problem Poor Medication Adherence

Agenda-Setting Report Issued to Reduce Adverse Health and Economic Consequences

WASHINGTON, DC--(Marketwire- August 1, 2007) - With mounting evidence that poor adherence to medication regimens has become America's other drug problem, the National Council on Patient Information and Education (NCPIE) -- the non-profit coalition of more than 100 organizations working to improve communication on the appropriate use of medicines -- today released a 10-step action plan to reduce the adverse health and economic consequences associated with this growing public health threat.

Issued as a nationwide call to action, the report -- "Enhancing Prescription Medicine Adherence: A National Action Plan" -- finds that poor medicine adherence has reached crisis proportions in the U.S. and around the world, leading to unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and even death. According to studies cited in the report, only about 50 percent of American patients typically take their medicines as prescribed, resulting in approximately $177 billion annually in direct and indirect costs to the U.S.economy. Besides an estimated $47 billion each year for drug-related hospitalizations, not taking medicines as prescribed has been associated with as many as 40 percent of admissions to nursing homes and with an additional $2,000 a year per patient in medical costs for visits to physicians' offices.

"Although the challenge of poor medication adherence has been discussed and debated extensively, the problem has generally been under-addressed as a serious public health issue and, as a result, has received little direct, systematic, or sustained intervention," said Ray Bullman, NCPIE'sExecutive Vice President. "This report is intended as a renewed nationwide call to action and is provided as a blueprint for improving medication adherence through patient information and education, health professional intervention, expanded research, and supportive government policies."

The report, prepared in consultation with a panel of specialists in public health, further calls for action to address the barriers to patient adherence for populations at greatest risk, including those with low health literacy, children and older Americans who tend to have more long-term, chronic illnesses and therefore, take more different medications as they age. Data from several research studies find that between 40 percent and 75 percent of older people do not take their medications at the right time or in the right amount. Other data point to the impact of poor adherence among children and teens where as few as 30 percent of adolescents take their asthma treatments as prescribed.

Designed to provide the most up-to-date information about the state of prescription medicine adherence in the U.S., the NCPIEreport cites numerous behavioral, social, economic, medical, and policy-related factors that contribute to poor adherence and must be addressed if rates are to improve. This includes lack of awareness among clinicians about basic adherence management principles, poor communication between patients and clinicians, operational aspects of pharmacy and medical practice, and professional barriers. Moreover, adherence improvement is affected by federal policies that provide insufficient funding for adherence-related research and federal and state laws and regulations that impact the availability of compliance assistance programs.

Taking Steps to Address Prescription Medicine Adherence

Although the challenge of poor medication adherence has been discussed and debated for at least three decades, the NCPIEreport finds that little has changed since 1997 when the organization issued a previous report, "Prescription Medicine Compliance: A Review of the Baseline Knowledge," advocating for a coordinated approach to improved medication adherence. Therefore, in 2007, NCPIEconvened a panel of leading experts to create consensus on 10 national priorities that can have the greatest impact in improving prescription medicine adherence in the U.S. Ultimately involving the support and active participation of many stakeholders -- the federal government, state and local government agencies, professional societies and health care practitioners, health educators, and patient advocates -- this platform calls for action in the following areas:

1. Elevate patient adherence as a critical health care issue.

The report states that until health care policy makers, practitioners and other stakeholders recognize the extent of non-adherence, its cost, and its contribution to negative health outcomes, this problem will not be solved.

2. Agree on a common adherence terminology that will unite all stakeholders.

Because a number of common terms -- compliance, adherence, persistence, and concordance -- are now being used concurrently, the report calls on the public health community to reach agreement on standard terminology that will unite stakeholders around the common goal of improving the self-administration of medical treatments.

3. Create a public/private partnership to mount a unified national education campaign to make patient adherence a national health priority.

With the goal of motivating patients and practitioners to take steps to improve medication adherence, the report advocates a national education campaign where all stakeholders coordinate resources and speak with one voice. This will entail creating a national clearinghouse to share information and coordinate activities managed by NCPIE, a professional society, or an academic institution.

4. Establish a multidisciplinary approach to compliance education and management.

There is a growing recognition that a multidisciplinary approach to medication taking behavior is necessary for patient adherence to be sustained. This has led NCPIEto promote a new model -- the "Medicine Education Team" -- in which the patient and all members of the health care team work together to treat the patient's condition, while recognizing the patient's key role at the center of the process.

5. Immediately implement professional training and increase the funding for professional education on patient medication adherence.

To give practitioners hands-on information about adherence management, the report calls on professional societies and recognized medical sub-specialty organizations to translate existing research findings into professional education through continuing education courses and lecture series on patient adherence issues.

6. Address the barriers to patient adherence for patients with low health literacy.

Because low health literacy and limited English proficiency are major barriers to adherence and deserve special consideration, the report calls for widespread adoption of existing tools to convey medicine instructions to the estimated 90 million Americans who have difficulty reading, understanding and acting upon health information.

7. Create the means to share information about best practices in adherence education and management.

Today, stakeholders have access to more than 30 years of research measuring the outcomes and value of adherence interventions. Building on

this foundation, the report calls for the federal government -- through the Adherence Research Network -- to begin collecting data on best practices in the assessment of patient readiness, medication management and adherence interventions, incentives that produce quality outcomes from adherence interventions, and measurement tools so that this information can be quantified and shared across specialties and health care facilities.

8. Develop a curriculum on medication adherence for use in medical schools and allied health care institutions.

To address the lack of awareness among clinicians about basic adherence management principles, the report advocates required courses at medical, nursing, pharmacy and dental schools as well as courses for faculty members that focus on adherence advancement and execution of medication-related problem solving.

9. Seek regulatory changes to remove roadblocks for adherence assistance programs.

A number of federal and state laws and policies now limit the availability of adherence assistance programs. These barriers must be identified for lawmakers and regulators to address. Key issues include clarifying provisions of the federal anti-kickback statute, and ensuring that federal and state laws related to patient privacy and the use of prescription data do not unduly limit pharmacy-patient communication about the importance of adhering to prescribed therapy.

10. Increase the federal budget and stimulate rigorous research on medication adherence.

Although the National Institutes of Health created the Adherence Research Network to identify research opportunities at its 18 Institutes and Centers, the Network has been inactive since 2002. Moreover, in 2000, when the Network was funding adherence research, the actual NIHdollars earmarked for testing interventions to improve medication-taking behavior was only $3 million in a budget of nearly $18 billion. Thus, a key priority is advocating for the Adherence Research Network to be re-invigorated and for NIHto significantly increase research funding to test adherence interventions and measure their effectiveness.

About the Report

To prepare this new report, NCPIEconvened a project advisory team from leading professional societies, voluntary health organizations, and patient advocacy groups in 2007 to assess the extent and nature of poor medicine adherence, its health and economic costs, and its underlying factors. These advisors also examined the current state of research funding and educational initiatives around patient adherence to determine where major gaps still exist.

Members of the project advisory team are:

-- MichaelEllwood, Director, Special Projects of the AmericanAcademyof Physician Assistants

-- LenLichtenfeld, M.D., Deputy Chief Medical Officer of the American Cancer Society

-- RuthM. Parker, M.D. Consultant on Health Literacy to the Executive Vice President and CEO of the AmericanCollegeof Physicians Foundation

-- DianeTuncer, National Director of External Communications of the

American Diabetes Association

-- PenelopeSolis, J.D., Regulatory Relations Manger of the American

Heart Association

-- SandraJ. Fusco-Walker, Director of Government Affairs of the Asthma

andAllergy Network / Mothers of Asthmatics

-- PhillipSchneider, Vice President of External Relations and Program

Development for the National Association of Chain Drug Stores Foundation

-- RebeccaBurkholder, Director of Health Policy of the National

Consumers League

-- HeidiRosvold-Brenholtz, Editorial Director and Managing Editor of the

National Women's Health Resource Center, Inc.

About NCPIE

Established in 1982, the National Council on Patient Information and Education is a diverse non-profit coalition that works to stimulate and improve the communication of information about the appropriate use of prescription and OTC medicines. NCPIE'smore than 100 members include consumer organizations: patient advocacy groups; voluntary health agencies; health professional associations, schools of pharmacy, nursing, and dentistry; health-related trade associations; prescription and over-the-counter pharmaceutical manufacturers; and local, state and federal government agencies. More information about NCPIEis available through its Web site: www.talkaboutrx.org.

Contact:
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THE HENRY J. KAISER FAMILY FOUNDATION kaisernetwork.org

Kaiser Daily Health Policy Report

Bd Public Ed

Tuesday, July 31, 2007

Prescription Drugs

Millions of Patients Not Taking Prescription Drugs Properly, Report Says

Millions of U.S. residents with chronic conditions either do not take medications correctly or stop taking them altogether, according to a report to be released this week by the National Council on Patient Information and Education, the AP/Peoria *Journal Star* reports. According to the report, people who initially are symptom-free are particularly at risk. For example, about half of hypertension patients follow their prescribed drug regimen, even though high blood pressure triples the risk of heart disease. The report also finds that adherence is an issue that crosses age groups and that the possibility of severe consequences for not taking recommended medications is insufficient to guarantee proper use. Poor adherence could be costing the nation as much as $177 billion in medical bills and lost productivity per year, and it is associated with up to 40% of nursing home admissions, the report finds (AP/Peoria *Journal Star*, 7/31).

Some experts say that the wording of directions for drug dosing is too confusing, the typeface on the labels is too small and the instruction materials are given in too many formats, according to the *AP/Houston Chronicle*. In an effort to curb the problem, the Agency for Healthcare Research and Quality is planning a campaign to improve treatment adherence, according to director Carolyn Clancy. She said, "We go into this with some humility," adding, "It's really pretty appalling how badly we do" (Neergaard, *AP/Houston Chronicle*, 7/30).

MEDICATION ADHERENCE

Medication non-adherence is "America's other drug problem."

It's huge...especially with drugs for "silent killers" such as hypertension, high cholesterol, osteoporosis, etc.

Patients stop taking HALF their chronic meds within a year. Up to one out of five new Rxs are never filled in the first place.

Poor adherence costs an estimated $100 billion/year... increases hospitalizations...and contributes to 125,000 deaths/year.

For example, patients who don't take their heart failure meds are twice as likely to die or be hospitalized. Patients who are not adherent to statin therapy seem to have TWICE the risk of heart attack.

Patients who don't use their asthma meds appropriately are more likely to go to the ER or be hospitalized for exacerbations.

This is a huge opportunity for pharmacists to help improve care...reduce expenditures...and earn revenue.

Pharmacists see patients 5 times more often than any other healthcare professional...and can do much to improve adherence.

Education is paramount. Many patients quit taking their meds because they don't know why they need them...don't think they are helping...believe the drug is harmful...or just plain forget.

Patients who understand the benefits are more likely to take their meds appropriately.

Use a "talk back" approach. Have patients tell you how and why they are taking their meds.

Tailoring drug regimens to the patient's lifestyle helps. Check for less expensive generics...meds with fewer doses...or a different side effect profile.

If appropriate, put the diagnosis on the Rx label...encourage use of a pillbox...give private counseling...use easy to read written materials...use refill reminder programs.

Give patients positive feedback on progress, and encourage patients to monitor their blood pressure, blood glucose, etc.

Go to our website for an excellent toolbox of resources and practical suggestions you can use to increase adherence.

Participate in Medication Therapy Management programs that recognize the value you add...and pay for pharmacy's contributions. 230811

Agenda Item 6

Board of Pharmacy
Web Site Redesign

California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: September 7, 2007

To: Members, Communication & Public Education Committee

Subject: New Board of Pharmacy Web Site

The Governor's Office has directed all state agencies to have a state-standardized Web site by November 1, 2007.

We have two staff working part time on this project, who estimate that that board is more than 25 percent complete in its conversion to the state new Web site design. The conversion will be completed on time. In the last month, staff has needed the assistance of the department's Web site designers for assistance with some of the more technical aspects; for example, we needed assistance with features of the search function.

A copy of the new Web site design will be distributed at the meeting.